

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

KING DRUG COMPANY OF
FLORENCE, INC.,
AMERISOURCEBERGEN CORP.,
AMERISOURCEBERGEN DRUG
CORP., BELLCO DRUG CO., H.D.
SMITH, LLC., CARDINAL HEALTH,
INC., THE HARVARD DRUG GROUP,
L.L.C., MCKESSON CORPORATION,
J M SMITH CORPORATION d/b/a
SMITH DRUG COMPANY,
BURLINGTON DRUG COMPANY, INC.,
THE NORTH CAROLINA MUTUAL
WHOLESALE DRUG COMPANY,
DAKOTA DRUG INC., VALUE DRUG
COMPANY and FWK HOLDINGS, LLC,

Plaintiffs,

v.

ABBOTT LABORATORIES, ABBVIE
INC., ABBVIE PRODUCTS LLC f/k/a
ABBOTT PRODUCTS LLC f/k/a ABBOTT
PRODUCTS, INC. f/k/a SOLVAY
PHARMACEUTICALS, INC., ACTAVIS
HOLDCO, U.S. INC., ACTAVIS, INC.
n/k/a ALLERGAN FINANCE, LLC and
f/k/a WATSON PHARMACEUTICALS,
INC., BESINS HEALTHCARE, INC., f/k/a
LABORATOIRES BESINS-ISCOVESCO
and BESINS-ISCOVESCO U.S., INC.,
PADDOCK LABORATORIES, INC. n/k/a
PADDOCK HOLDINGS LLC, PAR
PHARMACEUTICAL, INC., TEVA
PHARMACEUTICALS USA, INC., and
UNIMED PHARMACEUTICALS LLC,
f/k/a UNIMED PHARMACEUTICALS,
INC.

Defendants.

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs King Drug Company of Florence, Inc., AmerisourceBergen Corp., AmerisourceBergen Drug Corp., Bellco Drug Co., H.D. Smith, LLC, Cardinal Health, Inc., The Harvard Drug Group, L.L.C., McKesson Corporation, J M Smith Corporation d/b/a Smith Drug Company, Burlington Drug Company, Inc., The North Carolina Mutual Wholesale Drug Company, Dakota Drug Inc., Value Drug Company and FWK Holdings, LLC (collectively, “Plaintiffs”), by and through their undersigned attorneys, bring this action against Defendants AbbVie Inc., AbbVie Products LLC (f/k/a Abbott Products LLC f/k/a Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc.) (“Solvay”), Abbott Laboratories (“Abbott”), and Unimed Pharmaceuticals LLC (f/k/a Unimed Pharmaceuticals, Inc.) (“Unimed”), which operates as an indirect subsidiary of AbbVie Inc. (AbbVie Inc., AbbVie Products LLC, Solvay, Abbott, Unimed and their respective predecessors- and successors-in-interest are collectively referred to herein as “AbbVie”);¹ Besins Healthcare, Inc. (f/k/a Laboratoires Besins-Iscovesco and Besins-Iscovesco U.S., Inc.) (“Besins”); Actavis, Inc. (n/k/a Allergan Finance, LLC and f/k/a Watson Pharmaceuticals, Inc.), Actavis Holdco U.S., Inc. (Actavis, Inc., Allergan Finance LLC, Watson Pharmaceuticals, Inc. and Actavis Holdco U.S., Inc. are collectively referred to herein as “Watson”); Par Pharmaceutical, Inc. (“Par”) and Paddock Laboratories, Inc. (n/k/a Paddock Holdings LLC) (“Paddock”) (Par and Paddock are collectively referred to herein as “Par/Paddock”); and Teva Pharmaceuticals USA, Inc. (“Teva”) (collectively, “Defendants”). The allegations below are based upon personal knowledge as to those matters relating to Plaintiffs, and as to all other matters alleged, based on the investigations of counsel; publicly available materials

¹ The Complaint states when different corporate entities came into (and out of) existence and may use individual company names (*e.g.*, “Unimed,” or “Solvay”) to refer to those entities when the Complaint is referring to an action at a particular point in time. The Complaint, however, will generally use “AbbVie” to refer to these entities.

from *FTC v. Actavis, Inc.*, Nos. 09-cv-955, 09-2084 (N.D. Ga.), and associated cases; public filings in *FTC v. AbbVie Inc.*, No. 14-5151 (E.D. Pa.), including the Memorandum Opinion on Summary Judgment, 2017 WL 4098688 (E.D. Pa. Sept. 15, 2017) (ECF No. 300); the Findings of Fact issued by United States District Court Judge Harvey Bartle III following a three-week trial reported at *FTC v. AbbVie Inc.*, 329 F. Supp. 3d 98 (E.D. Pa. 2018) (“Findings of Fact”); and upon information and belief.

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages challenging an overarching course of anticompetitive conduct by AbbVie, as well as AbbVie’s anticompetitive agreements with each of Defendants Watson (and its successors), Par/Paddock (and its successors), and Teva, that have denied Plaintiffs the opportunity to purchase lower-priced generic versions of the blockbuster drug AndroGel and thereby caused Plaintiffs to suffer overcharges.² AndroGel is a testosterone replacement drug with hundreds of millions of dollars in net sales annually (more than \$3 billion from 2009-12 alone). To unlawfully maintain and extend their monopoly on AndroGel, AbbVie implemented an anticompetitive overarching scheme over nearly a decade to delay and exclude AB-rated³ and BX-rated generic AndroGel competition until the mid-2010s, a delay that bought AbbVie time to convert the market from AndroGel 1% to a line extension, AndroGel

²AndroGel comes in two strengths. AndroGel 1% was the original formulation that was approved by the FDA on February 28, 2000 and launched that year. A more concentrated version, AndroGel 1.62% was approved by the FDA on April 29, 2011 and launched immediately thereafter. This Complaint will use the term “AndroGel” to refer to AndroGel 1% and will refer to AndroGel 1.62% if that strength is specifically at issue.

³ AB-rated generic versions of brand name drugs contain the same active ingredients, and are found by the Food and Drug Administration (“FDA”) to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand-name drugs is their price: generics are priced below their brand counterparts. As discussed below, AbbVie (and Teva and Besins) also acted wrongfully to prevent a BX-rated generic version of AndroGel from entering the market, and a BX-rated generic also would have been priced below branded AndroGel and taken sales from it.

1.62%. Because generic versions of AndroGel 1% are not automatically substitutable for AndroGel 1.62%, however, this product switch served to further suppress generic competition and inflict even more overcharges on Plaintiffs. In furtherance of their overall scheme, AbbVie, *inter alia*: (a) entered into unlawful agreements in 2006 to share hundreds of millions of dollars of branded AndroGel profits with Watson over 9 years under the guise of a pretextual AndroGel co-promotion deal, to induce Watson to abandon its challenge to AbbVie's patent and agree not to compete against AndroGel with its AB-rated generic 1% testosterone gel until at the earliest August 31, 2015; (b) entered into unlawful agreements in 2006 to share tens of millions of dollars of branded AndroGel profits with Par/Paddock over several years under the guise of pretextual AndroGel co-promotion and back-up manufacturing deals, to induce Par/Paddock to abandon its challenge to AbbVie's patent and agree not to compete against AndroGel with their competing AB-rated generic 1% testosterone gel until at the earliest August 31, 2015; (c) filed sham patent lawsuits (with Besins) against Teva and Perrigo Company plc ("Perrigo") in 2011 for the purpose of interfering with, delaying, and blocking the market entry of Teva's and Perrigo's competing 1% generic testosterone gel products; and (d) entered into unlawful agreements in 2011 to pay Teva through an authorized generic deal relating to one of AbbVie's other blockbuster drugs, TriCor, which was worth over \$175 million to Teva, to induce Teva to abandon its challenge to AbbVie's baseless patent infringement claims over its generic AndroGel and agree not to enter the market with its competing 1% generic testosterone gel product until at the earliest December 27, 2014. Defendants' anticompetitive conduct thwarted generic competition for AndroGel and has forced Plaintiffs, who purchased branded AndroGel 1% and 1.62% directly from AbbVie, and purchased generic AndroGel 1% directly from generic manufacturers, to pay billions of dollars more for their AndroGel 1% and 1.62% purchases and/or their generic AndroGel 1% purchases than they would

have paid absent such unlawful conduct.

2. Typically, the launch of a generic drug brings huge cost savings to both direct purchasers like Plaintiffs, who buy substantial quantities of pharmaceuticals directly from brand drug manufacturers, and other purchasers, including consumers. Every state has adopted laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions automatically. Because of substitution laws and other institutional features of pharmaceutical distribution, the launch of AB-rated generics results in both a rapid price decline and a rapid shift in purchasing from brand to generic. Once generic competition begins, generics quickly capture sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months. These effects have been studied extensively by government and academic researchers, and by the drug manufacturers themselves.

3. Brand drug companies, like AbbVie, that market the more expensive branded drugs view generic entry and the savings it brings as a grave threat to their profits. As detailed below, AbbVie knew that they would lose enormous sales and profits on AndroGel once one or more generics entered the market and, as a result, devised a plan to delay generic entry from occurring.

4. The course of anticompetitive conduct by Defendants challenged herein consists of AbbVie's overarching scheme to delay and exclude generic competition for AndroGel implemented over nearly a decade, as well as each of the independently illegal components of the scheme.

5. AndroGel was launched in 2000 to great commercial success, but was not protected by any patent. The active ingredient in AndroGel – testosterone – was known and unpatentable. Without patent protection, AbbVie's regulatory exclusivity for AndroGel was set to expire on February 28, 2003, and AbbVie knew that applications seeking approval to market generic

versions of AndroGel would likely be filed immediately thereafter. To extend their monopoly, AbbVie hatched a scheme to maintain and extend their AndroGel monopoly, by, *inter alia*, obtaining a patent, listing that patent in the FDA's Orange Book, filing patent infringement litigation – regardless of merit – against would-be competitors to delay them from entering the market for up to 30 months, and then paying the would-be competitors to give up their respective patent fights and delay their generic entry.

6. Timing was critical to AbbVie's scheme. Generics need to file a Paragraph IV certification only with respect to the patents listed in the FDA's Orange Book. Absent a patent to list in the Orange Book, AbbVie would not be able to force would-be competitors to file a Paragraph IV certification and then trigger a 30-month stay of approval of the potential generics' applications by filing suit.

7. Thus, AbbVie (and Besins) filed a patent application on August 30, 2000, which later issued as U.S. Patent No. 6,503,894 ("894 patent"). The '894 patent claims a gel formulation containing testosterone and certain other ingredients in specified amounts, and its use. To obtain the '894 patent, AbbVie and Besins were required by the U.S. Patent and Trademark Office ("PTO") to significantly narrow their original patent claims. The companies' initial, broad claims sought to cover testosterone gel compositions containing *any* penetration enhancer. Penetration enhancers are inactive ingredients that facilitate the delivery of a drug product's active ingredient – testosterone in the case of AndroGel – through the skin and into the bloodstream. Ultimately, AbbVie and Besins claimed only a narrow group of formulations, all of which require a *single* enhancer known as isopropyl myristate ("IPM").

8. In their fervor to expedite issuance of the '894 patent, however, AbbVie and Besins botched the prosecution of the '894 patent. As issued on January 7, 2003, the '894 patent did not

claim AndroGel (or the testosterone drug substance that is a component of AndroGel) or an approved method of use for AndroGel. Nevertheless, AbbVie submitted the '894 patent for listing in the FDA's Orange Book on January 7, 2003 claiming that it "covers the composition, formulation, and/or method of use of AndroGel," so that they could delay FDA approval of any generic applications for AndroGel for up to 30 months – merely by filing a patent infringement suit.

9. On May 13 and 21, 2003, generic companies Watson and Paddock, respectively, filed applications with the FDA ("Abbreviated New Drug Applications" or "ANDAs") seeking approval to market generic versions of AndroGel. Watson and Paddock both certified under Paragraph IV that the '894 patent was invalid, unenforceable, and/or not infringed by their proposed generic products. Nevertheless, AbbVie and Besins sued Watson and Paddock for alleged infringement of the '894 patent on August 21, 2003. The lawsuits triggered automatic regulatory stays that blocked the FDA from granting final approval to Watson's and/or Paddock's bioequivalent generic versions of AndroGel for up to 30 months.

10. AbbVie and Besins knew that claims 1-30 of the '894 patent, as originally issued, did not claim AndroGel or Watson's or Paddock's proposed generic products, because those claimed compositions would be too caustic to be used on human skin. In an attempt to salvage the '894 patent, on June 12, 2003, AbbVie and Besins filed a request for a certificate of correction with the PTO, seeking to "correct" those claims. The PTO did not issue a certificate of correction of the '894 patent until December 16, 2003 – approximately four months after AbbVie and Besins had sued Watson and Paddock.

11. In the patent litigation, Watson asserted that the '894 patent was, among other things, invalid; and "[b]y following the expedient of merely filing this lawsuit – regardless of its

lack of merit – [AbbVie and Besins] automatically received the benefit of the 30-month statutory stay. This preserves [AbbVie’s and Besins’s] monopoly by preventing FDA from approving Watson’s ANDA until after the 30 months expire, unless the period is shortened by, *inter alia*, a court order”; and by engaging “in this meritless litigation and by improperly using it to obtain extended market exclusivity from FDA, [AbbVie and Besins] prevent the marketing of a generic version of 1 percent (1%) testosterone gel that would compete against [AbbVie’s and Besins’s] product and that would be a significant benefit to the public by providing equally effective medication at lower prices.”

12. In the patent litigation, Par/Paddock asserted that the ’894 patent was, among other things, invalid; and that the ’894 patent was “fatally botched,” a “sham,” that “the purported corrections [AbbVie and Besins] seek to make – insertion of 0.1N – does not even allow claim 9 to cover AndroGel,” and that “the Certificate is invalid and was improperly issued in any event.”

13. Rather than permitting the ’894 patent case to proceed to trial, which AbbVie and Besins reasonably would have expected to lose, on September 13, 2006, AbbVie agreed to share hundreds of millions of dollars of branded AndroGel profits with Watson, and tens of millions of dollars of branded AndroGel profits with Par/Paddock, in exchange for their agreements to give up their respective patent challenges, and not sell their respective AB-rated generic versions of AndroGel for nine years, until at the earliest August 31, 2015.

14. AbbVie disguised these “exclusionary payments” in pretextual agreements, claiming that the multi-million dollar payments were ostensibly for: (i) co-promotion of AndroGel (Watson and Par); and/or (ii) back-up manufacturing of AndroGel (Par/Paddock). The exclusionary payments constituted large and unexplained payments made to induce Watson and Par/Paddock to delay launching their respective generics until at least August 31, 2015. The

payments exceeded the amount of any litigation costs that AbbVie and Besins would have incurred had they continued their respective litigations until conclusion. AbbVie, Watson, and Par/Paddock intentionally concealed the true purpose and nature of the exclusion payments in an attempt to shield their exclusionary agreements from antitrust scrutiny.

15. AbbVie's agreements with Watson and Par/Paddock are anticompetitive because they apportioned to themselves the surplus from competitive generic entry that would have and should have accrued to Plaintiffs, as direct purchasers of AndroGel. In order to maintain supra-competitive pricing, AbbVie, Watson and Par/Paddock agreed to delay generic entry until at the earliest August 31, 2015 and share in the supra-competitive profits earned unlawfully during that period of delay. As such, AbbVie's agreements with Watson and Par/Paddock were also market allocation agreements among horizontal competitors. AbbVie's multi-million dollar payments to Watson and Par/Paddock compensated them for agreeing to delay their market entry. AbbVie knew that they would reap excess profits during that period of unlawful delay. The anticompetitive agreements with Watson and Par/Paddock, therefore, were in each of their financial interests, but harmed Plaintiffs who directly purchased AndroGel 1% and 1.62%, by causing Plaintiffs to be overcharged. The delay in generic competition also harmed consumers, competition, and consumer welfare.

16. AbbVie used the nearly ten-year period of generic delay to develop and market a more concentrated version of AndroGel 1% called AndroGel 1.62%, that was basically the same as AndroGel 1% except it allowed patients to use less gel volume. AbbVie switched sales from AndroGel 1% to AndroGel 1.62% before the end of 2014 so that when generic versions of AndroGel 1% finally launched, they would not be automatically substituted for prescriptions for AndroGel 1.62%, and therefore AbbVie would be able to continue to charge supra-competitive

prices for AndroGel 1.62% and nevertheless retain those sales. The product switch or “hop” from branded 1% to 1.62% also suppressed sales of generic AndroGel 1%. An AB-rated generic can be substituted automatically by pharmacies for the brand in filling prescriptions for the brand, but this automatic substitution applies only to the brand for which the generic is AB-rated. Hence, the lower the brand prescription volume at the time of generic entry, the lower the generic sales. Lowering the brand prescription volume of the original brand product in advance of generic entry, of course, is the whole point of a product switch for the brand company.

17. Before AbbVie was able to complete shifting the market to AndroGel 1.62%, their multi-billion dollar AndroGel franchise was once again threatened – this time, by two other generic manufacturers, Perrigo and Teva.

18. Recognizing the huge market potential for AndroGel and aware of the narrow scope of the '894 patent, Teva and Perrigo each developed generic versions of AndroGel that designed around the '894 patent – *i.e.* they did not use IPM, the penetration enhancer in AndroGel required by the patent claims, for their generic products. Perrigo's product used isostearic acid (“ISA”), and Teva's product used isopropyl palmitate (“IPP”). Because Teva's and Perrigo's products each used different penetration enhancers than AndroGel, Teva and Perrigo were required (due to a citizen petition filed by AbbVie) to seek FDA approvals to market their respective products by filing section 505(b)(2) New Drug Applications (“505(b)(2) applications”).⁴

19. Teva and Perrigo notified AbbVie and Besins that their respective proposed AndroGel products did not infringe the '894 patent. Teva did so on March 16, 2011, and Perrigo on September 20, 2011. Again faced with the near-term possibility of competition to branded

⁴ See generally, 21 U.S.C. § 355(b)(2); FDA, *Guidance for Industry: Applications Covered by Section 505(b)(2)* (Oct. 1999) available at <https://www.fda.gov/downloads/Drugs/Guidances/ucm079345.pdf>.

AndroGel, AbbVie and Besins filed sham patent litigation, suing Perrigo on October 31, 2011 and Teva on April 29, 2011, for alleged infringement of the '894 patent in order to trigger automatic 30-month stays on the FDA's authority to approve Teva's and Perrigo's generic products.

20. AbbVie and Besins filed their patent infringement lawsuits even though Teva's and Perrigo's products are clearly outside the literal scope of the '894 patent. In 2009, AbbVie and Besins decided not to assert that Perrigo's generic AndroGel formulation infringed the '894 patent. On July 17, 2009, AbbVie issued a press release announcing that "[a]fter careful evaluation" it had decided not to file a patent infringement suit against Perrigo, as Perrigo's product "contains a different formulation than the formulation protected by the AndroGel patent."

21. AbbVie and Besins had no reasonable basis to contend that Teva's and Perrigo's penetration enhancers are equivalent to IPM under the doctrine of equivalents. First, AbbVie and Besins surrendered Teva's and Perrigo's penetration enhancers while prosecuting the '894 patent before the PTO in order to obtain the '894 patent, and therefore are precluded from arguing equivalence under the well-settled doctrine of prosecution history estoppel.

22. Second, AbbVie and Besins disclosed, but did not claim, Teva's and Perrigo's penetration enhancers in the '894 patent and therefore dedicated them to the public.⁵

23. Third, AbbVie and Besins took precisely the opposite position at the PTO than they took in the patent litigation by arguing that different penetration enhancers are not interchangeable with, or equivalent to, one another. For example, AbbVie and Besins represented to the PTO that "testosterone gel products with different penetration enhancers cannot be demonstrated as

⁵ The claims of the '894 patent are also invalid, unenforceable and did not cover AndroGel or generic versions of AndroGel for additional reasons unrelated to the identity of the penetration enhancer.

substantially equivalent, *i.e.*, similar compositions” and that ISA (Perrigo’s penetration enhancer) “is not equivalent to and substitutable for” the penetration enhancer claimed in the ’894 patent.

24. Teva asserted counterclaims against AbbVie and Besins on June 6, 2011, alleging that the patent lawsuits they filed were anticompetitive and a sham. Perrigo notified AbbVie and Besins on September 20, 2011 that Perrigo’s product was outside the scope of the ’894 patent, and that an infringement action would constitute a sham.

25. In October 2011, the district court in the patent litigation against Teva scheduled a bench trial for May 2012 on the dispositive prosecution history estoppel issue. The early trial date posed a problem for AbbVie and Besins. A Teva victory would terminate the 30-month Hatch-Waxman stay, allowing Teva to obtain FDA approval and launch its product. To preserve their profits and buy more time to shift patients to AndroGel 1.62%, AbbVie needed another way to fend off Teva, and decided to pay Teva to defer any launch.

26. For Teva’s part, it also eventually decided that it would be better off being paid *not* to launch its generic AndroGel. According to the Federal Trade Commission (“FTC”), Teva settled the baseless infringement claims and abandoned its counterclaims after agreeing to refrain from launching any generic AndroGel product until at the earliest December 27, 2014, in exchange for a large and unjustified payment in the form of a highly profitable TriCor authorized generic supply deal from AbbVie. The AndroGel settlement and TriCor authorized generic supply deal were executed on the same day, December 20, 2011, and were two sides of a single anticompetitive agreement. The large unexplained payment made to Teva exceeded the amount of any litigation costs that AbbVie would have incurred had they continued the litigation until conclusion.

27. AbbVie had no independent, standalone reason to supply Teva with generic TriCor, which would accelerate generic competition on that blockbuster product. But the TriCor deal

made perfect sense as a *quid pro quo* for Teva's agreement to forgo competition with AndroGel. According to the FTC, AbbVie calculated that it would sacrifice about \$100 million in TriCor sales, but that was a small fraction of the billions of dollars in branded AndroGel revenue AbbVie projected it would obtain by deferring generic AndroGel competition for three years (from December 2011 to December 2014). And the delay bought AbbVie time to protect the AndroGel franchise by continuing to shift the market to AndroGel 1.62%.

28. AbbVie's and Besins's lawsuit against Perrigo had been filed in a different judicial district than the suit against Teva, and Perrigo believed that its case was unlikely to end before the suit against Teva. AbbVie and Perrigo began settlement discussions by November 3, 2011, shortly after the patent litigation was filed. Under the terms of an FTC consent order Perrigo signed in 2011, AbbVie could not pay Perrigo to defer entry of its generic, but they could offer Perrigo something else it highly valued – the right to launch generic AndroGel at the same time as Teva. A settlement, therefore, provided what Perrigo believed to be an opportunity to achieve parity with Teva (that is, the same entry date) without expending any litigation costs. Without a settlement, Perrigo believed it would have been unable to achieve parity with Teva because the 30-month stay blocking FDA approval of Perrigo's product would remain in effect even after Teva's 30-month stay would expire. Thus, on December 8, 2011, AbbVie, Besins and Perrigo agreed to settle their patent litigation, and the terms of the settlement provided that Perrigo could launch its generic AndroGel upon the launch of another generic AndroGel product or earlier under other undisclosed circumstances.

29. Perrigo's decision to settle was driven not by the strength of AbbVie's and Besins's patent claims against it (which were baseless), but by the competitive position Perrigo found itself in as a result of the 30-month stay triggered by the baseless lawsuit and the opportunity to improve

that position by achieving parity with Teva. But as AbbVie knew – and Perrigo did not – AbbVie was in the process of negotiating a deal with Teva that would delay Teva’s entry well beyond what Perrigo expected. By securing Teva’s agreement to forgo entry, AbbVie blocked competition from Perrigo as well. Because of the terms of Perrigo’s settlement, the Teva agreement effectively protected AbbVie and Besins against Perrigo’s generic AndroGel entry until December 2014.

30. As a result of Defendants’ anticompetitive conduct, generic competition for AndroGel 1% – which would have begun in approximately January 2007 for the Watson and/or Par/Paddock’s generic products absent the improper payments to delay competition, by approximately June 2012 (via, at least, a BX-rated product) but for AbbVie’s and Besins’s sham litigation against Teva and AbbVie’s reverse payment to Teva, and by approximately June 2013 but for AbbVie’s and Besins’s baseless lawsuit against Perrigo – did not actually begin until December 27, 2014.

31. Defendants’ anticompetitive conduct further harmed Plaintiffs because the unlawful delay in generic competition allowed AbbVie to shift a significant amount of sales from AndroGel 1%, the original dosage strength of the drug, to AndroGel 1.62%, allowing AbbVie to charge high, monopolistic prices for AndroGel 1.62% despite available generic versions of AndroGel 1% because the brand AndroGel 1.62% product is not subject to automatic substitution with generic AndroGel 1% products. This product “switch” or “hop” thereby suppressed sales of generic versions of AndroGel 1%.

32. As generic competition nears or begins, brand companies also often launch “authorized generics” to retain some revenue they would otherwise lose to generic competition. An “authorized generic” is the same as the brand, and launched under the brand’s New Drug Application, but labeled and priced like a generic. AbbVie likely would have launched an

authorized generic version of AndroGel 1% whenever another generic product would have entered. Thus, there would have been at least one additional generic version of AndroGel 1% on the market no later than June 2013, in addition to Perrigo's, but for the unlawful conduct alleged in this Complaint. As a matter of pharmaceutical economics, prices fall most dramatically when two or more generic equivalents of a drug are on the market alongside a brand name product. Thus, Plaintiffs would have paid even lower prices if an authorized generic version launched alongside the first generic product.

33. As a result of Defendants' anticompetitive misconduct, Plaintiffs were forced to pay substantially higher prices for AndroGel 1%, AndroGel 1.62% and for the generic versions of AndroGel 1% that eventually launched than they would have paid absent Defendants' anticompetitive misconduct.

II. JURISDICTION AND VENUE

34. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover treble damages and the costs of suit, including reasonable attorneys' fees, for the injuries sustained by Plaintiffs resulting from violations by Defendants, as herein alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

35. Defendants transact business within this judicial district, and the interstate trade and commerce hereinafter described is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

36. Section 5 of the Clayton Act, 15 U.S.C. § 16(i), tolls the limitations period for private antitrust actions during the time that a related government case is pending: "Whenever any civil or criminal proceeding is instituted by the United States to prevent, restrain, or punish

violations of any of the antitrust laws . . . the running of the statute of limitations in respect to every private or State right of action arising under said laws and based in whole or in part on any matter complained of in said proceeding shall be suspended during the pendency thereof and for one year thereafter.” *See also Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.*, No. CV 15-6480, 2019 WL 130535, at *9-10 (E.D. Pa. Jan. 8, 2019).

37. The FTC filed a civil antitrust proceeding against Solvay, Unimed, Paddock, Watson, and Par in the Central District of California on January 27, 2009, which case was transferred to the Northern District of Georgia on April 8, 2009, concerning the first part of the exclusionary scheme – the payments to Watson and Par/Paddock to delay entry of their generic AndroGel products – described in this Complaint. *See FTC v. Actavis, Inc.*, No. 09-955 (N.D. Ga.) (ECF Nos. 1, 71). On February 28, 2019, the FTC and AbbVie, the last remaining defendant in that action, announced a settlement of the *FTC v. Actavis*, Northern District of Georgia, litigation. *See id.* (ECF No. 868); *see also* <https://www.ftc.gov/news-events/press-releases/2019/02/last-remaining-defendant-settles-ftc-suit-led-landmark-supreme>.

38. The FTC also filed a civil antitrust action in this Court on September 26, 2014 involving the second part of the exclusionary scheme described in this Complaint—the filing of sham lawsuits against Teva and Perrigo and the reverse payment to Teva, *see FTC v. AbbVie*, 2:14-cv-0515-HB (E.D. Pa.) (ECF No. 1), concerning violations of the antitrust laws based on the conduct alleged in this Complaint. A three-week bench trial on the sham litigation claims was held in that case in 2018, and the Court issued its Findings of Fact, dated June 29, 2018 (*see* 329 F. Supp. 3d 98 (E.D. Pa. 2018)). That litigation is on appeal in the Third Circuit.⁶

⁶ The Court dismissed the reverse payment allegations as to AbbVie’s payment to Teva (*FTC v. AbbVie, Inc.*, 107 F. Supp. 3d 428 (E.D. Pa. 2015)), and ruled that the FTC had not established that Teva would have launched but for

39. Courts routinely apply Clayton Act § 16(i) to actions initiated by the FTC. *See Minn. Min. and Mfg. Co. v. N.J. Wood Finishing Co.*, 381 U.S. 311, 321-22 (1965).

40. There is also statute of limitations tolling pursuant to *American Pipe & Const. Co. v. Utah*, 414 U.S. 538 (1974) and *Crown, Cork & Seal Company, Inc. v. Parker*, 462 U.S. 345 (1983), which hold that the filing of a class action tolls the running of the statute of limitations for absent class members to bring individual suits until the court has denied certification.

41. The first private class action complaint on behalf of a putative class of direct purchasers of AndroGel against AbbVie, Watson (now Actavis), and Par concerning the first part of the exclusionary scheme – the reverse payments to Watson and Par/Paddock to delay entry of their generic AndroGel products – was filed on February 2, 2009 in the Central District of California (*see Meijer Inc. v. Unimed Pharm., Inc.*, C.A. No. 5:09-cv-00215 (C.D. Cal.) (ECF No. 1)), which was followed shortly by additional direct purchaser class actions in that district. Those actions were transferred to the Northern District of Georgia on April 8, 2009. *American Pipe* tolled the statute of limitations for Plaintiffs' claims related to, *inter alia*, the first part of the scheme until at least the denial of class certification in the Northern District of Georgia litigation on July 16, 2018. A class action complaint on behalf of direct purchasers challenging the second part of the exclusionary scheme – the filing of sham litigation against Teva and Perrigo – was filed in this Court on July 2, 2018. *See Value Drug Co. v. AbbVie Inc.*, 2:18-cv-02804 (ECF No. 1). That case has been stayed pending a decision by the Third Circuit Court of Appeals in *FTC v. AbbVie, Inc.* C.A. 14-5151. *Id.* at ECF No. 5.

the sham lawsuit against it (329 F. Supp. 3d at 140), but the FTC has appealed. *See FTC v. AbbVie, Inc.*, Nos. 18-2621, 18-2748, 18-2758 (3d Cir.).

III. THE PARTIES

42(a). Plaintiff King Drug Company of Florence, Inc. (“King Drug”) is a corporation organized under the laws of North Carolina, and formerly located at 605 W. Lucas Street, Florence, South Carolina 29501 with a current mailing address of 2207 Sterling Place, Wilmington, NC 28403. King Drug purchased AndroGel 1% directly from AbbVie, and was injured by the illegal conduct alleged herein by paying overcharges.

42(b). Plaintiff AmerisourceBergen Corp. is incorporated in Delaware with a principal place of business at 1300 Morris Drive, Chesterbrook, PA 19087. Subsidiaries of AmerisourceBergen Corp. purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel 1% directly from generic manufacturers during the relevant period, and were injured by the illegal conduct alleged herein by paying overcharges.

42(c). Plaintiff AmerisourceBergen Drug Corp., a subsidiary of AmerisourceBergen Corp., is incorporated in Delaware with a principal place of business at 1300 Morris Drive, Chesterbrook, PA 19087. AmerisourceBergen Drug Corp. purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel 1% directly from generic manufacturers during the relevant period, and was injured by the illegal conduct alleged herein by paying overcharges.

42(d). Plaintiff Belco Drug Co., a subsidiary of AmerisourceBergen Corp., is incorporated in New York with a principal place of business at 5500 New Horizons Boulevard, N. Amityville, NY 11701. Belco Drug Co. purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel 1% directly from generic manufacturers during the relevant period, and was injured by the illegal conduct alleged herein by paying overcharges.

42(e). Plaintiff H.D. Smith, LLC, a subsidiary of AmerisourceBergen Corp., is organized under the laws of Delaware with a principal place of business at 3063 Fiat Avenue, Springfield, IL 62703. H.D. Smith LLC purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel 1% directly from generic manufacturers during the relevant period, and was injured by the illegal conduct alleged herein by paying overcharges.

42(f). Plaintiff Cardinal Health, Inc. is incorporated in Ohio with its principal place of business at 7000 Cardinal Place, Dublin, OH 43017. Cardinal Health, Inc., through one or more of its subsidiaries, purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel 1% directly from generic manufacturers, and was injured by the illegal conduct alleged herein by paying overcharges.

42(g). Plaintiff The Harvard Drug Group, L.L.C. (“Harvard”), is a wholly owned subsidiary of Generic Drug Holdings, Inc., which is a wholly-owned subsidiary of HDG Acquisition, Inc., which is a wholly-owned subsidiary of Cardinal Health 110, LLC, which is a wholly-owned subsidiary of Cardinal Health, Inc. Harvard is a limited liability company organized under the laws of Michigan with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, MI 48152. Harvard purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel 1% directly from generic manufacturers during the relevant period, and was injured by the illegal conduct described herein by paying overcharges.

42(h). Plaintiff McKesson Corporation is incorporated in Delaware with a principal place of business in Las Colinas, Texas. McKesson Corporation purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel directly from generic manufacturers, and was injured by the illegal conduct alleged herein by paying overcharges.

42(i). Plaintiff J M Smith Corporation d/b/a Smith Drug Company (“Smith Drug”) is incorporated in South Carolina with its principal place of business at 9098 Fairforest Road, Spartanburg, South Carolina 29301. Smith Drug purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel directly from generic manufacturers, and was injured by the illegal conduct alleged herein by paying overcharges.

42(j). Plaintiff Burlington Drug Company, Inc. (“Burlington Drug”) is incorporated in Vermont with its principal place of business at 91 Catamount Drive, Milton, Vermont 05468. Burlington Drug purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel directly from generic manufacturers, and was injured by the illegal conduct alleged herein by paying overcharges.

42(k). Plaintiff The North Carolina Mutual Wholesale Drug Company (“Mutual Drug”) is incorporated in North Carolina and its principal place of business is located at 816 Ellis Road, Durham, North Carolina 27703. Mutual Drug purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel directly from generic manufacturers, and was injured by the illegal conduct alleged herein by paying overcharges.

42(l). Plaintiff Dakota Drug Inc. is incorporated in North Dakota and its principal place of business is located at 1101 Lund Boulevard, Anoka, Minnesota 55303. Dakota Drug purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel directly from generic manufacturers, and was injured by the illegal conduct alleged herein by paying overcharges.

42(m). Plaintiff Value Drug Company is a corporation organized under the laws of the State of Pennsylvania and is located at 195 Theater Drive, Duncansville, Pennsylvania 16635. Value Drug purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased

generic AndroGel directly from generic manufacturers, and was injured by the illegal conduct alleged herein by paying overcharges.

42(n). Plaintiff FWK Holdings, LLC (“FWK”) is organized under the laws of the State of Illinois with a principal place of business in Glen Ellyn, Illinois. FWK is the assignee of the claims of Frank W. Kerr Co. Frank W. Kerr Co. purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel directly from generic manufacturers, and was injured by the illegal conduct alleged herein by paying overcharges.

43. Defendant Abbott Laboratories (together with its affiliates, “Abbott”) is a publicly traded, for-profit company incorporated in Illinois with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. In 2010, Abbott acquired Solvay Pharmaceuticals, Inc. and Solvay Pharma U.S. Holdings, Inc. After the acquisition, Solvay became Abbott’s wholly-owned subsidiary and was renamed Abbott Products Inc. On January 1, 2013, Abbott separated into two independent, publicly traded companies – Abbott and AbbVie Inc. – through the distribution of 100 percent of the issued and outstanding common stock of AbbVie Inc. to Abbott’s shareholders. Abbott is a diversified medical products company engaged in the business of, among other things, developing, manufacturing, marketing, and distributing medical devices, diagnostic systems and tests, and nutritional products. Prior to January 1, 2013, Abbott’s portfolio of products included brand-name pharmaceuticals, including AndroGel. In the twelve months ending December 31, 2012 (the last year before AbbVie’s separation), Abbott had net sales of approximately \$30.9 billion. As used in this Complaint, “Abbott” encompasses relevant predecessors- and successors-in-interest.

44. Defendant AbbVie Inc. is incorporated in Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. has existed since

January 1, 2013, as a publicly traded, pharmaceutical company with Abbott's former portfolio of proprietary pharmaceuticals and biologics, including AndroGel. AbbVie Inc. includes the former entities Solvay Pharmaceuticals, Inc. and Solvay Pharma U.S. Holdings, Inc., which Abbott acquired in 2010, as well as Abbott Products, Inc. and Abbott Products U.S. Holdings, Inc. AbbVie Inc. is engaged in the business of, among other things, developing, manufacturing, marketing, distributing, and selling brand-name pharmaceutical products, including AndroGel. In the twelve months ending December 31, 2013, AbbVie had net sales of approximately \$18.8 billion, of which more than \$1 billion were U.S. sales of AndroGel 1% and 1.62%.

45. In 2010, when Abbott acquired Solvay Pharmaceuticals, Inc., Solvay was renamed Abbott Products Inc. In 2012, Abbott Products Inc. was renamed Abbott Products LLC, which then changed its name to AbbVie Products LLC. In January 2013, AbbVie Products LLC assumed all of Abbott's proprietary pharmaceutical business.

46. Defendant AbbVie Products LLC f/k/a Abbot Products LLC f/k/a Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc., has continuously owned Unimed Pharmaceuticals, LLC from 1999 to the present. AbbVie Products LLC is a for-profit entity with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois. AbbVie Products LLC is a wholly owned subsidiary of AbbVie Inc.

47. Defendant Unimed Pharmaceuticals, LLC f/k/a Unimed Pharmaceuticals, Inc. (together with its affiliates, "Unimed"), is a for-profit entity, with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois. It is a wholly-owned indirect subsidiary of AbbVie Inc. In July 1999, Solvay Pharmaceuticals, Inc. acquired Unimed. As used in this Complaint, "Unimed" encompasses relevant predecessors- and successors-in-interest. Defendants in paragraphs 43-47, above, will be referred to, collectively, as "AbbVie."

48. Defendant Besins Healthcare, Inc., f/k/a Laboratoires Besins-Iscovesco and Besins-Iscovesco U.S., Inc. (together with its affiliates, “Besins”) is a for-profit corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 607 Herndon Parkway, Suite 210, Herndon, Virginia 20170. Besins includes the former entities Laboratoires Besins-Iscovesco and Besins-Iscovesco U.S., Inc. Besins is a wholly-owned subsidiary of Besins Healthcare S.A., a privately held corporation with its headquarters in Brussels, Belgium. Besins is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing brand-name pharmaceutical products. Under an agreement with AbbVie, Besins manufactures AndroGel and receives a share of the profits from U.S. sales. As used in this Complaint, “Besins” encompasses relevant predecessors- and successors-in-interest.

49. Defendant Actavis, Inc. n/k/a Allergan Finance, LLC and f/k/a Watson Pharmaceuticals, Inc. develops and manufactures generic and branded pharmaceutical products. On January 24, 2013, Watson announced that it had adopted Actavis, Inc. as its new global name and would begin trading under the symbol ACT on the New York Stock exchange. Actavis, Inc. is now known as Allergan Finance, LLC. As used in this Complaint, “Watson” encompasses Defendants “Actavis Holdco” and Actavis, Inc. and their relevant predecessors- and successors-in-interest.

50. Defendant Actavis Holdco U.S., Inc. (“Actavis Holdco”) is a Delaware corporation with its principal place of business at 3411 Silverside Road, Wilmington, Delaware 19810. In March 2015, Actavis plc, the parent company of Defendant Actavis, Inc. merged with Allergan plc (“Allergan”) and adopted Allergan’s name. In August 2015, Teva Pharmaceuticals Industries Ltd., an Israeli company, acquired Allergan’s generic business, Actavis Generics. As part of this acquisition, Teva Pharmaceuticals Ltd. acquired Actavis Holdco, as well as its subsidiary Watson

Laboratories Inc., a manufacturer of generic drugs. At present, Actavis Holdco is a direct subsidiary of Defendant Teva Pharmaceuticals USA, Inc., which is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

51. Defendant Par Pharmaceutical, Inc. (together with Par Pharmaceutical Companies, Inc., “Par”) is a New York corporation with its principal place of business in Chestnut Ridge, New York. Par is a subsidiary of Endo International plc, an Irish corporation with its U.S. headquarters located in Malvern, Pennsylvania. In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par, and combined it with its existing generics subsidiary, Qualitest Pharmaceuticals, naming the combined unit, Par Pharmaceutical, Inc. As used in this Complaint, “Par” encompasses relevant predecessors- and successors-in-interest.

52. Defendant Paddock Laboratories, Inc. (n/k/a Paddock Holdings LLC) (“Paddock”) is a privately-held pharmaceutical company located in Minneapolis, Minnesota. Paddock principally develops, manufactures and markets generic versions of brand name drugs. Since July 26, 2011, it has operated as a subsidiary of Perrigo Company plc. As used in this Complaint, “Paddock” encompasses relevant predecessors- and successors-in-interest. Par and Paddock are collectively referred to herein as “Par/Paddock.”

53. Defendant Teva Pharmaceuticals USA, Inc. (“Teva”), is a for-profit corporation organized and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Teva is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. Teva is engaged in the business, *inter alia*, of developing, manufacturing, marketing and distributing generic pharmaceuticals.

54. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in conducting Defendants' affairs (or that of their predecessors- or successors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

IV. FACTUAL ALLEGATIONS

A. The Regulatory Structure for Approval of Drugs.

55. The approval of brand-name and generic drugs in the United States is governed by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355 and § 271. *See* Pub. L. No. 98-417, 98 Stat. 1585 (the "Hatch-Waxman Act" or "Hatch-Waxman"). These laws establish a lengthy procedure for obtaining approval of a new drug and an abbreviated procedure for generic approval to facilitate competition from lower-priced generic drugs.

56. A drug manufacturer seeking to market a new drug must obtain approval from the FDA. *See* 21 U.S.C. §355(a). There are three pathways established by the FDCA and Hatch-Waxman: (1) a section 505(b)(1) New Drug Application ("NDA"); (2) a section 505(b)(2) application, and (3) a section 505(j) Abbreviated New Drug Application ("ANDA").

57. An NDA is a full-length application containing information on the drug's safety and efficacy, an explanation of the drug's ingredients, a description of the methods used in the manufacture and packaging of the drug, samples of the proposed labeling, and samples of the drug. *See id.* § 355(b)(1). The NDA must also contain a list of any patents covering the drug. *Id.*

58. Once the FDA has approved a brand manufacturer's NDA, the brand manufacturer must list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly called the "Orange Book") any patent that the brand manufacturer certifies (1) claims either the approved drug product or approved methods of using the drug product, and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization prior to the expiration of the listed patent(s). Any appropriate patent issued after NDA approval must be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2). The FDA relies completely on the brand manufacturer's certification about its patents, as the FDA does not have the resources or authority to verify for accuracy or trustworthiness the manufacturer's assertions regarding its patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

59. After the FDA has approved a brand-name drug (also referred to as the Reference Listed Drug ("RLD")), an applicant seeking to market a generic version of that drug can obtain approval through abbreviated procedures. *See* 21 U.S.C. § 355(j). Most commonly, the generic applicant will file a section 505(j) ANDA stating, among other things, that the generic has the same active ingredient and is biologically and pharmacologically equivalent to the brand-name drug. *Id.* at §355(j)(2)(A). The generic applicant may then rely on the safety and efficacy data contained in the NDA for the brand-name drug. *Id.*

60. A generic drug containing certain modifications from the brand-name drug may file a section 505(b)(2) application, which is a hybrid between an ANDA and a full NDA. *See* 21 C.F.R. § 314.54. The applicant must submit additional data to the FDA demonstrating that any differences between the brand-name drug and the generic will not affect safety and efficacy but

can otherwise avoid the other clinical studies necessary for a full NDA application. *Id.*; *see also Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 227 (3d Cir. 2013).

61. Congress enacted Hatch-Waxman to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also included provisions allowing for the extension of patent terms to recover time spent developing certain types of new pharmaceutical products, thereby bolstering pharmaceutical companies' financial incentives to create new and innovative products.

62. Hatch-Waxman achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic revenues for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled \$21.6 billion; by 2013, total prescription drug revenue had climbed to more than \$329.2 billion, with generic drugs accounting for 86% of prescriptions.⁷ Generics are now dispensed 95% of the time when a generic form is available.⁸

B. Mechanism for Brand and Generic Drug Manufacturers to Resolve Patent Disputes

63. The Hatch-Waxman Act also provides specialized procedures for parties to resolve intellectual property disputes.

64. To obtain FDA approval of an ANDA or a section 505(b)(2) application, a generic manufacturer must certify that the generic drug proposed in its application will not infringe any valid and enforceable patents listed by the brand-name manufacturer in the Orange Book for the

⁷*See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014).

⁸ *Id.* at 51.

brand name drug. Under Hatch-Waxman, a generic applicant's ANDA or section 505(b)(2) application must contain one of four certifications:

- a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
- b. that the patent for the brand drug has expired (a "Paragraph II certification");
- c. that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or
- d. that the patent for the brand drug is invalid, unenforceable, and/or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

65. If a generic manufacturer files a Paragraph IV certification that the listed patent is invalid, unenforceable, and/or will not be infringed, it must serve timely notice to the brand manufacturer.

66. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notice of the Paragraph IV certification, the FDA will not grant final approval to the ANDA or section 505(b)(2) application until the earlier of (a) the passage of thirty months from the date of receipt of the notice of the Paragraph IV certification (the "30-month stay"), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA or section 505(b)(2) application. The FDA may grant tentative approval to a generic application containing a Paragraph IV certification when it determines that the application would otherwise be ready for final approval but for the existence of a patent or regulatory exclusivity, such as the 30-month stay.

67. If a brand manufacturer does not file suit within 45 days of receiving notification of the Paragraph IV certification, it can still file suit later, but it will not be entitled to a 30-month

stay, and the FDA will not be prevented from granting final approval to the application assuming other regulatory requirements are satisfied.

C. The Competitive Effects of AB-Rated Generic Competition.

68. Once the FDA approves a generic drug, the applicant may request from the FDA a therapeutic equivalence (“TE”) rating. A TE rating is a code that reflects the FDA’s determination regarding whether a generic product is pharmaceutically and biologically equivalent to the referenced-listed drug. Products that are determined to be therapeutically equivalent are assigned an “A” or “AB” rating. Generic products for which there is insufficient data to confirm bioequivalence are assigned a “B” or “BX” rating.

69. “A” or “AB” rated generic versions of brand drugs are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between an “A” or “AB” rated generic and its corresponding brand version is price. Because “A” or “AB” rated generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. On average, generics are around 30% less expensive than their brand counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for all drug purchasers.

70. Since the passage of the Hatch-Waxman Act, every state has adopted laws that either require or permit pharmacies to automatically substitute “A” or “AB” rated generic equivalents in filling brand prescriptions (unless the prescribing physician has specifically ordered otherwise). Because of these drug substitution laws and other institutional features of pharmaceutical distribution, the launch of “A” or “AB” rated generics results both in a rapid price

decline and a rapid sales shift in purchases from the brand to generics. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months.

71. When multiple generic competitors enter the market, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.⁹ In a 2010 study, the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%.¹⁰ As a result, competition from “A” or “AB” rated generic drugs is viewed by brand drug companies as a grave threat to their bottom line.

72. Generic competition enables direct purchasers to: (a) purchase generic versions of a drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

73. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the “patent cliff” – the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. According to the Congressional

⁹See, e.g., Patricia Danzon & Li-Wei Chao, Does Regulation Drive Out Competition in Pharmaceutical Markets? J.L. & ECON. (Oct. 2000); Tracy Regan, Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the Waxman-Hatch Act (Univ. of Miami, Dep't of Econ., Working Paper, Feb. 14, 2004); R. Frank, The Ongoing Regulation of Generic Drugs, NEW ENG. J. MED., v. 357, pp. 1993-96 & n.20 (Nov. 2007).

¹⁰See FTC, Pay-for-Delay: How Drug Company Pay-offs Cost Consumers Billions (Jan. 2010) (“FTC Pay-for-Delay Study”), available at <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

Budget Office, generic drugs save consumers an estimated \$8 billion to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.¹¹

74. Until an “A” or “AB” rated generic version of the brand drug enters the market, however, there is no therapeutically equivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supra-competitive prices. Brand manufacturers, such as AbbVie, are well aware that generics will rapidly take their brand sales. Brand manufacturers thus seek to stall the impact of generic competition for as long as possible, sometimes (as here) resorting to illegal means. As discussed below, Teva also forecast that a BX-rated generic AndroGel would be priced below the brand and take significant sales from the brand.

D. AndroGel

75. AndroGel is a brand-name transdermal testosterone gel product approved by the FDA for the treatment of hypogonadism, a clinical syndrome that results from the failure of a man’s body to produce adequate amounts of testosterone. It is estimated that this condition affects 2-6% of the adult male population in the United States.¹² Patients with hypogonadism are typically treated with testosterone replacement therapy (“TRT”) whereby exogenous testosterone is administered.

76. AndroGel was developed through a collaboration between Unimed and various subsidiaries of Besins’s parent company, and at the time of its launch, AndroGel 1% was marketed and distributed by Solvay Pharmaceuticals, Inc., then the parent company of Unimed. Abbott

¹¹FDA WEBSITE, GENERIC DRUGS UNDERGO RIGOROUS FDA SCRUTINY, *available at* <https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny>.

¹²Hypogonadism is a lifelong condition that causes decreases in energy and libido, erectile dysfunction, and changes in body composition including decreased bone density.

Laboratories acquired Solvay and Unimed in February 2010. At that time Solvay was renamed Abbott Products Inc. In 2012, Abbott Products Inc., was renamed Abbott Products LLC, which then changed its name to AbbVie Products LLC. In January 2013, AbbVie Products LLC assumed all of Abbott's proprietary pharmaceutical business; AbbVie Products LLC is a wholly owned subsidiary of AbbVie Inc. From June 2000 to 2012, Besins and its corporate affiliates manufactured for AbbVie all AndroGel sold in the United States.

77. As Judge Bartle found in the Findings of Fact he issued in *FTC v. AbbVie*, the first TRTs approved by the FDA were injectables in which testosterone is dissolved in a liquid and then injected into a muscle of the body. Injectable testosterone were introduced in the 1950s and have been available in generic form for decades. They are administered every one to three weeks. While many patients receive injections at their doctors' office, some patients opt to self-administer injections at home or visit clinics specializing in TRTs commonly known as "Low-T" centers. Testosterone injections typically require two needles: a withdrawal needle and an injection needle. Because a deep intramuscular injection is required, this treatment method may cause pain and discomfort. Injectables generally provide an initial peak in testosterone level at the time of injection followed by troughs or valleys as the injection wears off. This variation in testosterone level may cause swings in mood, libido, and energy.

78. TRTs may also be administered through a gel or patch which is applied to the skin thereby allowing the testosterone to be absorbed into the bloodstream. This group of products is known as topical testosterone replacement therapies or transdermal testosterone replacement therapies ("TTRTs").

79. AbbVie Inc.'s predecessor Unimed received FDA approval for AndroGel in February 2000 "for replacement therapy in males for conditions associated with deficiency or absence of endogenous testosterone."

80. In June 2000, AbbVie Inc.'s predecessor Solvay, which had acquired Unimed, began marketing AndroGel in the United States. Solvay sold AndroGel at prices far above what Solvay paid Besins for the drug. Thus, even accounting for other direct expenses that Solvay allocates to selling and marketing AndroGel, the drug was highly profitable for Solvay.

81. AndroGel was launched as the first FDA-approved testosterone gel. It is applied once a day to one or more application sites, including the upper arms, shoulders, and abdomen. AndroGel now comes in two strengths: (1) 1%, which was the original formulation launched in June 2000; and (2) 1.62%, which was first sold in or about May 2011. When AndroGel 1% came on the market in 2000, it was available only in sachets (small, single-dose packages). In 2004 it became available in a metered-dose pump. AbbVie discontinued the AndroGel 1% pump in December 2013.

82. Transdermal gels have several advantages over the other forms of TRTs. A gel is relatively easy for a patient to apply without the potential pain and discomfort associated with an injection. It also allows the patient to maintain a relatively steady testosterone level with less significant peaks and troughs. As compared to the patch form of testosterone, it has a lower rate of irritation and is not visible.

E. AndroGel Was Launched Without Patent Protection, and AbbVie Hatched a Plan to Extend Their Monopoly

83. When Solvay began marketing AndroGel in the United States in June 2000, it did so without any patent protection. Testosterone, the active ingredient contained in AndroGel, is

unpatentable and AbbVie knew that. Patents covering the synthesis of artificial testosterone expired decades ago. Testosterone has been available in various drug products since the 1950s. Pharmaceutical gel products have also been available for decades.

84. Without patent protection, under Hatch-Waxman, AbbVie's new dosage form exclusivity¹³ for AndroGel would expire on February 28, 2003, and ANDAs seeking approval to market generic versions of AndroGel were likely to be filed immediately thereafter. AbbVie hatched a scheme to delay generic competition by obtaining a patent, listing that patent in the FDA Orange Book under NDA No. 21-015 for AndroGel, delaying would-be competitors from entering the market for up to 30 months by suing them for alleged patent infringement regardless of merit and then paying the would-be competitors to give up their respective patent fights and delay their generic entry.

85. Timing was critical to AbbVie's scheme. Generics are required to file Paragraph IV certifications only with respect to patents listed in the FDA's Orange Book. Absent a patent to list in the Orange Book, AbbVie would not be able to force would-be competitors to file Paragraph IV certifications, and without such a certification against a listed patent, AbbVie would not be able to trigger a 30-month stay of FDA approval of a generic application merely by filing a patent infringement lawsuit.

¹³ A three-year period of exclusivity is granted for a drug product that contains an active moiety that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. For example, the changes in an approved drug product that affect its active ingredient(s), strength, dosage form, route of administration or conditions of use may be granted exclusivity if clinical investigations were essential to approval of the application containing those changes.

1. AbbVie Rushed to Obtain a Patent to Purportedly Protect AndroGel from Generic Competition before their Regulatory Exclusivity Expired, and Botched its Prosecution.

86. AbbVie did not seek patent protection for AndroGel until two months after the drug was launched commercially in the United States. On August 30, 2000, AbbVie and Besins filed United States Patent Application Serial No. 09/651,777 (“the ’777 application”) with the PTO. The ’894 patent issued from the ’777 application on January 7, 2003. AbbVie and Besins and/or its affiliates jointly owned the ’777 application and jointly own the ’894 patent.

87. The ’894 patent does not claim testosterone itself or methods of using testosterone generally, but rather covers a very narrowly-defined group of pharmaceutical gel formulations containing testosterone and other listed ingredients in certain amounts, and their use. Namely, the patent claims formulations containing specified amounts of (1) testosterone; (2) ethanol or isopropanol; (3) a gelling agent; and (4) the penetration enhancer IPM. Some of the claims also require the presence of sodium hydroxide or water, while other claims require the absence of those compounds. All of the claims of the ’894 patent require IPM in the compositions, formulations, or methods of use thereof.

88. In their race to expedite issuance of the ’894 patent, AbbVie and Besins botched its prosecution. As a result, as explained below, AbbVie and Besins could not reasonably have believed that the ’894 patent as originally issued was properly listed in the Orange Book or infringed by the products that were the subject of Watson’s or Paddock’s ANDAs.

89. FDA regulations in effect at the time provided that “[f]or patents that claim a drug substance or drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product. For patents that claim a method of use, the

applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application.” 21 C.F.R. § 314.53. As explained below, the then-existing claims of the ’894 patent did not support Orange Book listing because the ’894 patent did not claim AndroGel (or the testosterone drug substance that is a component of AndroGel) or an approved method of use for AndroGel.

90. It is well settled law that “[o]ne who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that [independent] claim.” *Wahpeton Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1552 (Fed. Cir. 1989). As a result, unless AndroGel (or an approved method of using AndroGel) fell within the scope of one of the five originally-issued independent claims (*i.e.*, claims 1, 9, 10, 18 and 31) of the ’894 patent, it could not fall within the scope of any of the remaining originally-issued claims in the ’894 patent. Each of the originally-issued claims 1, 9, 10 and 18 required a formulation or composition having at least “about 1%” sodium hydroxide. As AbbVie and Besins admitted in pleadings from the patent litigation against Watson and Paddock, the phrase “sodium hydroxide” in the originally-issued ’894 patent claims means the pure (anhydrous) form of sodium hydroxide. In addition, AbbVie and Besins admitted that the amount of sodium hydroxide recited in these claims is 50 to 250 times greater than the amount of sodium hydroxide in AndroGel marketed under NDA No. 21-105.

91. It was therefore implausible that a trier-of-fact would find that originally-issued claims 1, 9, 10 or 18 (or the claims depending therefrom) covered either (1) AndroGel (or the testosterone drug substance that is a component of AndroGel) or any generic version of AndroGel or (2) an approved method of use for AndroGel or any generic version of AndroGel. To the contrary, AbbVie and Besins admit that a skilled pharmaceutical chemist would recognize that the amount of pure (anhydrous) sodium hydroxide recited in originally-issued claims 1, 9, 10, and 18

is “far too caustic to be used on human skin.”

92. Neither originally-issued independent claims 1, 9, 10 and 18 nor the claims depending from those claims could reasonably justify the inclusion of the ’894 patent in the Orange Book. The sole remaining independent claim, Claim 31, likewise could not reasonably be construed to cover a method for using the AndroGel product or a generic version of the AndroGel product. Claim 31 requires, among other things, a “*pharmaceutical composition consisting essentially of*: (i) about 0.5% to about 5% testosterone; (ii) about 0.1% to about 5% isopropyl myristate; (iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and (iv) about 0.1% to about 5% of a gelling agent. . . .” (emphasis added). The transition “consisting essentially of” indicates that a claim “necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Thus, for a particular pharmaceutical composition to meet the limitations of claim 31, it (1) must ***include*** testosterone, isopropyl myristate, a gelling agent, and either ethanol or isopropanol in the required amounts; and (2) further must ***exclude*** any additional ingredient that materially affects the basic and novel properties of the invention.

93. The briefing that AbbVie and Besins filed in their patent infringement litigation against Watson and Par/Paddock admitted that the basic and novel properties of the invention include the ability to produce plasma levels of testosterone sufficient to be effective in the treatment of hypogonadal patients. Both water and sodium hydroxide materially affect the basic and novel properties of the purported invention because, *inter alia*, they materially affect the claimed formulation’s ability to produce plasma levels of testosterone sufficient to be effective in the treatment of hypogonadal patients. Under these circumstances, it is unreasonable to believe

that claim 31 encompassed a method for using AndroGel. Thus, neither claim 31 nor any of its dependent claims could have justified AbbVie in submitting the '894 patent for listing in the Orange Book.

a. AbbVie and Besins initially sought to include all penetration enhancers in their patent claims

94. AbbVie and Besins had to significantly narrow their patent claims over the course of the '894 patent prosecution, including their claims as to the scope of penetration enhancers in the formulation, in order to convince the PTO to issue the patent. In the written description of their invention filed with their original patent application, AbbVie and Besins identified “[n]on-limiting examples” of penetration enhancers that could be used in a testosterone gel, including “C8-C22 fatty acids such as isostearic acid, octanoic acid, and oleic acid [and] lower alkyl esters of C8-C22 fatty acids such as ethyl oleate [and] isopropyl myristate. . . .”

95. In their original patent application, AbbVie (through AbbVie Inc.’s predecessor, Unimed) and Besins sought to cover all of these penetration enhancers – and more – in the scope of their patent claims. In their broadest form, AbbVie’s and Besins’s claims attempted to cover a formulation containing “a penetration enhancer,” along with other ingredients.

96. In June 2001, the patent examiner rejected the composition claims in the original patent application as obvious over prior art. The examiner stated that prior publications disclosed both the use of testosterone in pharmaceutical products delivered through the skin and the use of various penetration enhancers in pharmaceutical compositions. In particular, the examiner cited international patent applications filed by Mak et al. (WO 99/24041) and Allen et al. (WO 96/27372). These publications collectively disclosed the use of several specific penetration

enhancers, including IPM (the penetration enhancer contained in AndroGel), IPP (the penetration enhancer contained in Teva's product), and oleic acid, among others.

b. AbbVie and Besins attempted to include a group of 24 penetration enhancers in their patent claims

97. In response to the patent examiner's rejection and to secure allowance of the patent, on October 19, 2001, AbbVie and Besins amended their claims. The amendment narrowed the broadest claims to a testosterone gel formulation containing at least one penetration enhancer selected from a group of 24 specifically listed compounds and classes of compounds, a group which included IPM (the penetration enhancer contained in AndroGel) and ISA (the penetration enhancer contained in Perrigo's product) but not IPP (the penetration enhancer contained in Teva's product). To avoid an obviousness rejection, AbbVie and Besins argued that their narrowed claims were patentable because the prior art recognized differences between penetration enhancers, and the claimed penetration enhancers were not substitutable with the penetration enhancers disclosed in the prior art.

98. In their arguments and in a declaration from a company executive, AbbVie and Besins also pointed to data showing that the AndroGel formulation unexpectedly displayed a "smooth pharmacokinetic profile" and asserted that this profile, *inter alia*, had led to AndroGel's commercial success. AbbVie and Besins did not file data showing that unexpected results would be achieved by a testosterone gel formulation containing a penetration enhancer other than IPM.

99. During a December 6, 2001 interview with the patent examiner, AbbVie and Besins discussed the pending claims and the October 19, 2001 amendment. The examiner told AbbVie and Besins that two of the 60 pending claims were patentable over prior art. These two claims recited a formulation with *only one* penetration enhancer, IPM, in specified amounts. AbbVie and

Besins argued during the interview that another pending claim, listing both IPM and the penetration enhancer lauryl alcohol, was novel and nonobvious, but the examiner did not accept this argument.

100. In response to the patent examiner's rejection and to secure allowance of the patent, AbbVie and Besins filed a supplemental amendment on December 21, 2001. The supplemental amendment canceled the prior claims to a testosterone gel formulation containing one of 24 specifically identified penetration enhancers and narrowed the scope of the claimed penetration enhancer to *IPM only*, the penetration enhancer contained in AndroGel. By disclaiming other penetration enhancers, AbbVie and Besins avoided the prior art of record, including Mak et al., cited by the patent examiner.

101. By choosing to claim IPM only, AbbVie and Besins dedicated to the public the rest of the penetration enhancers they disclosed but did not claim, including "C8-C22 fatty acids such as isostearic acid [*i.e.*, ISA]," the penetration enhancer in Perrigo's product, and "esters of C8-C22 fatty acids" such as IPP, the penetration enhancer in Teva's product.

102. The PTO issued a Notice of Allowability for the '894 patent on August 13, 2002. In describing the reasons for allowance, the patent examiner noted that AbbVie's and Besins's amendments, including the October 19, 2001 amendment (canceling claims listing "a penetration enhancer") and the December 21, 2001 amendment (canceling claims listing penetration enhancers other than IPM), "all together have been considered and are sufficient to remove the prior art rejection." The examiner further stated that "the prior art does not teach or fairly suggest the instant claimed pharmaceutical composition consisting essentially of the specific ingredients herein in the particular amounts."

103. The PTO issued the '894 patent to AbbVie and Besins on January 7, 2003. IPM is the only penetration enhancer included in the claims of the '894 patent and is required by each of those claims.

104. The '894 patent is listed in the Orange Book as purportedly covering AndroGel. The patent is scheduled to expire in 2020.

c. None of the originally-filed claims in the '777 application recited sodium hydroxide

105. In prosecuting the patent application relating to AndroGel, AbbVie and Besins submitted to the patent examiner multiple disclosure statements identifying hundreds of articles and patents discussing previous testosterone and hormone therapies, together with copies of each of these hundreds of articles and patents in multiple notebooks, comprising several feet of materials for the examiner to attempt to review. In addition, AbbVie and Besins filed hundreds of additional pages of papers, responses, amendments, and declarations.

106. As described in a report by the United States Government Accountability Office, patent examiners are generally expected to process an average of 87 patent applications per year and have an average time limit totaling 19 hours to process each application from its filing through its final acceptance or rejection. These time quotas are reinforced by examiners' bonus compensation, which is largely tied to the number of applications processed to completion. The patent application process is an ex parte process in which patent examiners rely upon the information and candor of applicants. The vast majority of all patent applications are ultimately granted.

107. The '777 application and '894 patent are directed to pharmaceutical compositions containing testosterone gel formulations and methods of using these compositions to treat

hypogonadism.

108. None of the originally filed claims in the '777 application recited sodium hydroxide, whose chemical symbol is "NaOH." Indeed, the sole reference to sodium hydroxide in the entire specification is in Table 5 (reproduced below), which discloses a single formulation having a very specific amount (*i.e.*, 4.72 grams) of a very specific sodium hydroxide solution (*i.e.*, 0.1 N NaOH).

V. TABLE 5

<u>Composition of AndroGel®</u>	
AMOUNT (w/w) SUBSTANCE	PER 100g OF GEL
Testosterone	1.0g
Carbopol 980	0.90g
Isopropyl myristate	0.50g
0.1 N NaOH	4.72g
Ethanol (95% w/w)	72.5g*
Purified water (qsf)	100.0g

*corresponding to 67g of ethanol

109. Nowhere did the '777 application disclose the concept of a range of sodium hydroxide concentrations in the pharmaceutical formulation. The phrase "0.1 N" indicates that the sodium hydroxide is in a dilute solution (roughly 4 grams of sodium hydroxide per 1000 grams of solution), as opposed to the pure (anhydrous) form of sodium hydroxide. 4.72 grams of a 0.1 N NaOH solution contains approximately 0.019 grams of sodium hydroxide and approximately 4.70 grams of water. Thus, the overall concentration of sodium hydroxide concentration in the AndroGel formulation described in Table 5 was roughly 0.019 percent (0.019 grams in a total of 100 grams of formulation).

d. AbbVie and Besins amended the original claims

110. On October 29, 2001, AbbVie and Besins filed an Amendment with the PTO that cancelled certain originally-filed claims and added others. New dependent claims 45 and 64 recited sodium hydroxide. In both of these new dependent claims, the term “sodium hydroxide” appears alone without any indication of either (1) a range (*e.g.*, “about 1% to about 5%”) or (2) a modifier indicating that the recited amount reflected the weight of a dilute solution (*e.g.*, “0.1 N”) rather than the weight of pure (anhydrous) sodium hydroxide. The remarks in the submission did not mention either these dependent claims or sodium hydroxide.

111. On December 21, 2001, AbbVie and Besins filed a Supplemental Amendment, canceling dependent claims 45 and 64 and adding new claims. Neither the new claims nor the applicants’ remarks mentioned sodium hydroxide.

112. On February 8, 2002, AbbVie and Besins filed a Second Supplemental Amendment. Among other things, the Second Supplemental Amendment changed all independent claims (except for one) to recite weight ranges for pure (anhydrous) sodium hydroxide, *i.e.*, “about 1% to about 5%” and “about 1% to about 3%.” None of those proposed claims referred to the weight ranges as referring to a dilute solution (*e.g.*, 0.1 N). As support for these claims, AbbVie and Besins cited Table 5 and stated: “Note that 4.72g of 0.1 N NaOH = about 1.8g NaOH in 100g of gel, or about 1.8%.” By making that statement – *i.e.*, by converting the 4.72 grams of a 0.1 N solution of sodium hydroxide in AndroGel to a measure of pure (anhydrous) sodium hydroxide – AbbVie and Besins demonstrated the intent to express the sodium hydroxide limitation in the claims as pure sodium (anhydrous) hydroxide rather than as a 0.1 N solution. The remarks did not otherwise mention sodium hydroxide.

113. While the 1.8g NaOH in 100g of gel is within the range of “about 1% to about 5%”

and “about 1% to about 3%” range recited in the then newly-added claims, there was no other calculation involving sodium hydroxide supplied by AbbVie and Besins supporting this range.

114. Significantly, the calculation converting the 4.72g of 0.1N NaOH to its equivalent amount in pure form in the AndroGel composition was in error by a factor of roughly 100. That is, the equivalent amount of pure sodium hydroxide in the AndroGel composition in Table 5 is not 1.8 grams, but rather about 0.018 grams per 100 grams of gel.

115. Subsequent to filing the Second Supplemental Amendment, AbbVie and Besins further amended the claims reciting sodium hydroxide on two separate occasions, but on neither occasion did AbbVie or Besins seek to amend the claims to recite the ranges for sodium hydroxide in a solution by inserting “0.1 N” or the like. By way of summary: (1) the specification of the ’777 application provides no written description support for any range of concentrations of sodium hydroxide (whether pure or in solution) and the sole mention of sodium hydroxide is a single amount of a very specific concentration of a sodium hydroxide solution in a single formulation as reflected in Table 5; and (2) when claims were later added reciting ranges of sodium hydroxide – additions for which there was absolutely no written description support – those ranges indisputably referred to ranges of amounts of pure (anhydrous) sodium hydroxide rather than ranges of amounts of a dilute sodium hydroxide solution such as 0.1 N.

2. The ’894 Patent Issues

116. On January 7, 2003, the ’894 patent issued. The five independent claims (*i.e.*, claims 1, 9, 10, 18, and 31) as originally issued recite:

1. A pharmaceutical composition, consisting essentially of:
 - a. about 0.5% to about 10% testosterone;
 - b. about 30% to about 98% alcohol selected from the group consisting

- of ethanol and isopropanol;
 - c. about 0.1% to about 5% isopropyl myristate;
 - d. about 1% to about 5% sodium hydroxide; and
 - e. about 0.1% to about 5% of a gelling agent, wherein the percentages of components are weight to weight of the composition.
- 9. A hydroalcoholic gel formulation, consisting essentially of:
 - a. about 1% to about 2% testosterone;
 - b. about 50% to about 75% ethanol;
 - c. about 0.5% to about 2% isopropyl myristate;
 - d. about 1% to about 3% sodium hydroxide;
 - e. about 0.5% to about 2% polyacrylic acid; and
 - f. water in an amount sufficient to make the formulation 100%; wherein the percentages of components are weight to weight of the formulation.
- 10. A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:
 - a. about 0.5% to about 5% testosterone;
 - b. about 30% to about 98% ethanol;
 - c. about 0.1% to about 5% isopropyl myristate;
 - d. about 1% to about 5% sodium hydroxide; and
 - e. about 0.1% to about 5% of a gelling agent; wherein the percentages of components are weight to weight of the composition.
- 18. A method for administering an active agent to a human subject in need thereof, the method comprising:
 - a. providing a phannaceutical [sic] composition consisting essentially of:
 - (i) about 0.5% to about 5% testosterone;
 - (ii) about 0.1% to about 5% of a gelling agent;
 - (iii) about 0.1% to about 5% isopropyl myristate;
 - (iv) about 1% to about 5% sodium hydroxide; and
 - (v) about 30% to about 98% alcohol selected form the group consisting of ethanol and isopropanol; wherein the percentages are weight to weight of the composition; and
 - b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject so as to

achieve a serum concentration within a range between about 300 ng testosterone per dl serum to about 1050 ng testosterone per dl serum within at least about 36 hours of daily dosing of the composition.

31. A method for administering an active agent to a human subject in need thereof, the method comprising:
 - a. providing a pharmaceutical [sic] composition consisting essentially of:
 - (i) about 0.5% to about 5% testosterone;
 - (ii) about 0.1% to about 5% isopropyl myristate;
 - (iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and
 - (iv) about 0.1% to about 5% of a gelling agent; wherein the percentages are weight to weight of the composition; and
 - b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject wherein serum concentration is substantially maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.

Thus, each of claims 1, 9, 10, and 18 (and necessarily each of their dependent claims) specifies that pure sodium hydroxide accounts for at least “about 1%” of the formulation on a “weight to weight basis.”

3. AbbVie Improperly Lists the '894 Patent in the Orange Book to Obtain the Benefit of the 30-Month Stay Under Hatch-Waxman

117. As issued on January 7, 2003, the '894 patent did not claim AndroGel (or the testosterone drug substance that is a component of AndroGel) or an approved method of use for AndroGel.

118. However, to obtain the benefits of the Hatch-Waxman 30-month stay, AbbVie was required to list the '894 patent in the Orange Book within 30 days of its issuance, and AbbVie did so. In submitting the '894 patent for listing, AbbVie also was required to submit a declaration signed under oath pursuant to 21 C.F.R. § 314.53 certifying that one or more of the issued claims

of the '894 patent covered AndroGel, or an approved method of using AndroGel, and that the '894 patent could reasonably be asserted against a person who engaged in the unauthorized manufacture, use, or sale of AndroGel. As discussed below, that declaration was false.

F. Watson and Paddock File Applications to Market Generic AndroGel; AbbVie and Besins Sue Them for Alleged Patent Infringement to Automatically Stay Approval of the Generic Applications for up to 30 Months

119. On May 13, 2003, Watson submitted to the FDA ANDA No. 76-737, for approval of its AB-rated generic version of AndroGel. Watson's ANDA contained a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by its ANDA. Watson notified AbbVie on July 8, 2003 that Watson had filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by Watson's ANDA.

120. Following Watson's 2003 ANDA filing and Paragraph IV certification, in August 2003, AbbVie (through AbbVie Inc.'s predecessor Unimed) and Besins sued Watson for alleged infringement of the '894 patent, filing a complaint against Watson in the Northern District of Georgia (the case was captioned *Unimed Pharmaceuticals Inc. v. Watson Pharmaceuticals, Inc.*, No. 1:03-cv-2501-TWT (N.D. Ga.)), alleging that Watson's filing of its ANDA for its proposed generic AndroGel product infringed one or more claims of the '894 patent.

121. On May 21, 2003, Defendant Paddock filed with the FDA ANDA No. 76-744, for approval of Paddock's AB-rated generic equivalent to AndroGel. Paddock's ANDA contained a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by its ANDA. Paddock notified AbbVie that Paddock had filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by Paddock's ANDA.

122. Paddock sought a partner to share the costs and risks associated with litigation relating to the '894 patent, together with the rewards from a successful outcome.

123. Following Paddock's 2003 ANDA filing and Paragraph IV certification, in August 2003, AbbVie (through AbbVie Inc.'s predecessor Unimed) and Besins, filed a complaint against Paddock in the Northern District of Georgia (the case was captioned *Unimed Pharmaceuticals Inc. v. Paddock Laboratories, Inc.*, No. 1:03-cv-2503-TWT (N.D. Ga.)), alleging that Paddock's filing of its ANDA for its proposed generic AndroGel product infringed one or more claims of the '894 patent.

124. On October 8, 2003, Paddock entered an agreement with Par, a generic company, in which Par agreed to share litigation expenses associated with Paddock's patent infringement litigation concerning the '894 patent, sell Paddock's generic AndroGel product after final FDA approval, and split the profits from sales of generic AndroGel with Paddock. Par entered into the licensing agreement only after conducting diligence on Paddock's ANDA in light of Solvay's '894 patent.

125. Pursuant to the Hatch-Waxman Act, the filing of the lawsuits against Watson and Par/Paddock triggered a stay during which the FDA was precluded from granting final approval to the generics' ANDAs for generic AndroGel 1% for up to thirty months.

126. At the time that they filed suit against Watson and Par/Paddock in August 2003 for alleged infringement of the '894 patent, AbbVie and Besins could not reasonably have believed that the manufacture, use, or sale of the generic AndroGel products that were the subject of Watson's or Par/Paddock's ANDAs would infringe the then-existing claims of the '894 patent (*i.e.*, putting aside the certificate of correction, discussed below). Watson's and Par/Paddock's proposed generic versions of AndroGel did not have anywhere near "about 1%" sodium hydroxide as

required by originally-issued independent claims 1, 9, 10 and 18 (and their dependent claims). As AbbVie and Besins admit, the amount of pure (anhydrous) sodium hydroxide recited in originally-issued claims 1, 9, 10, and 18 is “far too caustic to be used on human skin.” Thus, Watson’s and Par/Paddock’s ANDA products could not reasonably contain, and AbbVie and Besins could not reasonably have believed that Watson’s and Par/Paddock’s ANDA products contained, the amount of sodium hydroxide required by these patent claims. Therefore, AbbVie and Besins should not have asserted originally issued claims 1, 9, 10 or 18 (or the claims depending therefrom) against Watson and Par/Paddock.

127. That AbbVie and Besins knew that they had no basis for asserting claims 1, 9, 10 and 18 (and their dependent claims) (as originally issued) against Watson and Par/Paddock when they filed suit in August 21, 2003 is reflected by their prior filing of a Request for Certificate of Correction on June 12, 2003. No later than June 12, 2003, AbbVie and Besins knew of the fundamental defect in these claims and the impropriety of asserting them against Watson and Par/Paddock. Likewise, AbbVie and Besins undoubtedly knew of the defect in the sole remaining independent claim 31 – namely, the combination of a narrow transition “consisting essentially of” and the absence of a limitation reciting sodium hydroxide or water, both of which were critical components of the AndroGel formulation and the generic AndroGel formulations. AbbVie and Besins nevertheless filed suit.

128. Watson specifically alleged in its answer and counterclaims that (1) the ’894 patent was invalid because the patented subject matter was in public use and/or on sale in this country more than one year prior to the application; (2) the ’894 patent was unenforceable due to inequitable conduct before the PTO because persons owing a duty of candor withheld from the PTO information concerning pre-critical date sales and commercial transaction information with

intent to deceive; (3) AbbVie and Besins lacked a reasonable and good faith basis to allege infringement; (4) AbbVie and Besins filed the infringement action without substantial justification for the wrongful and anticompetitive purpose of extending their unlawful monopoly by invoking the 30-month stay; and (5) patent misuse. In detailing the bases for its affirmative defenses, Watson described the infringement litigation against it as “meritless” and alleged that AbbVie and Besins were “improperly using [the litigation]” to obtain extended market exclusivity from FDA and to prevent FDA from approving Watson’s product.

129. In response to the infringement suit, Paddock and Watson also filed counterclaims seeking a declaratory judgment that their respective generic products did not infringe and/or that the ’894 patent was invalid.

130. Recognizing the fatal flaws in the ’894 patent as issued, Watson and Par/Paddock moved for summary judgment of invalidity as to certain claims in the patent. Watson and Par/Paddock also would have moved for summary judgment of non-infringement following the claim construction ruling by the Court had they not entered into the unlawful reverse payment agreements challenged herein.

131. Both fact and expert discovery concluded by July 2005, *i.e.*, discovery had closed more than a year before the patent litigation was settled.

132. The summary judgment briefing between AbbVie and Besins and Watson relating to invalidity was completed on January 19, 2006, *i.e.*, it had been pending for approximately 9 months before the patent litigation was settled. The only summary judgment briefing between AbbVie and Besins and Par/Paddock relating to the invalidity motions that remained as of the date of settlement was the submission of Par/Paddock’s reply briefs.

133. As a result of the facts and circumstances detailed above, each of AbbVie, Besins, Watson, and Par/Paddock knew (or should have known) that, because the patent claims were very weak, absent the settlements, AbbVie and Besins would have lost the '894 patent litigation on the merits.

G. AbbVie and Besins Attempt to “Correct” the Botched Patent Claims

134. AbbVie and Besins knew that claims 1-30 of the '894 patent, as originally issued, did not claim AndroGel or Watson's or Paddock's proposed generic products, because the compositions claimed in the patent would be too caustic to be used on human skin.

135. In an attempt to salvage the patent, on or about June 12, 2003, AbbVie and Besins requested that the PTO “correct” many claims of the '894 patent. As AbbVie and Besins knew, the '894 patent as issued did not claim the generic AndroGel product that was the subject of Watson's and Par/Paddock's ANDAs. This is because, *inter alia*, like the FDA-approved AndroGel product, Watson's and Paddock's generic AndroGel products do not contain the concentration levels of pure sodium hydroxide required by claims 1-30 of the '894 patent as issued.

136. AbbVie and Besins knew that Watson and Par/Paddock did not plan on marketing the compositions in claims 1-30 of the '894 patent because *inter alia* those compositions would be too caustic to be used on human skin.

137. AbbVie and Besins sought to “correct” this by filing a Request for a Certificate of Correction (“COC”) with the PTO. Among other things, the request sought to add the phrase “0.1 N” before the term “sodium hydroxide” in claims 1, 9, 10, and 18 of the '894 patent. AbbVie and Besins represented to the PTO that the “mistakes were made in good faith and that the proper language is contained throughout the specification, see, for example, column 13, Table 5 (‘0.1 N NaOH’ (sodium hydroxide)).” AbbVie and Besins stated that the “correction would not introduce

any new matter and would not alter the substance of the patent in any way that would necessitate reevaluation by the Examiner.” AbbVie and Besins did not disclose to the PTO that (1) the reference to “0.1 N NaOH” appeared only once in (rather than “throughout”) the specification; and (2) the change *did* introduce “new matter” because the specification nowhere disclosed any ranges for “0.1 N NaOH” as recited by the purportedly “corrected” claims.

138. The COC issued on December 16, 2003. Following issuance of the COC, the five independent claims (*i.e.*, claims 1, 9, 10, 18, and 31) recite

1. A pharmaceutical composition, consisting essentially of:
 - a. about 0.5% to about 10% testosterone;
 - b. about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;
 - c. about 0.1% to about 5% isopropyl myristate;
 - d. about 1% to about 5% 0.1 N sodium hydroxide; and
 - e. about 0.1% to about 5% of a gelling agent, wherein the percentages of components are weight to weight of the composition.
9. A hydroalcoholic gel formulation, consisting essentially of:
 - a. about 1% to about 2% testosterone;
 - b. about 50% to about 75% ethanol;
 - c. about 0.5% to about 2% isopropyl myristate;
 - d. about 1% to about 3% 0.1 N sodium hydroxide;
 - e. about 0.5% to about 2% polyacrylic acid; and
 - f. water in an amount sufficient to make the formulation 100%; wherein the percentages of components are weight to weight of the formulation.
10. A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:
 - a. about 0.5% to about 5% testosterone;
 - b. about 30% to about 98% ethanol;

- c. about 0.1% to about 5% isopropyl myristate;
 - d. about 1% to about 5% 0.1 N sodium hydroxide; and
 - e. about 0.1% to about 5% of a gelling agent; wherein the percentages of components are weight to weight of the composition.
18. A method for administering an active agent to a human subject in need thereof, the method comprising:
- a. providing a pharmaceutical composition consisting essentially of:
 - (i) about 0.5% to about 5% testosterone;
 - (ii) about 0.1% to about 5% of a gelling agent;
 - (iii) about 0.1% to about 5% isopropyl myristate;
 - (iv) about 1% to about 5% 0.1 N sodium hydroxide; and
 - (v) about 30% to about 98% alcohol selected from [sic] the group consisting of ethanol and isopropanol; wherein the percentages are weight to weight of the composition; and
 - b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject so as to achieve a serum concentration within a range between about 300 ng testosterone per dl serum to about 1050 ng testosterone per dl serum within at least about 36 hours of daily dosing of the composition.
31. A method for administering an active agent to a human subject in need thereof, the method comprising:
- a. providing a pharmaceutical composition consisting essentially of:
 - (i) about 0.5% to about 5% testosterone;
 - (ii) about 0.1% to about 5% isopropyl myristate;
 - (iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and
 - (iv) about 0.1% to about 5% of a gelling agent; wherein the percentages are weight to weight of the composition; and
 - b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject wherein serum concentration is substantially maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.
139. A COC, however, only applies to causes of action that arise *after* the issuance of

the COC. This rule reflects the policy that the issuance of a patent serves a public notice function; patentees have a duty to prepare carefully their patent applications and then to police their patents when issued for accuracy and correctness to determine whether they contain any errors that require a COC.

140. Pursuant to 35 U.S.C. § 271(e)(2)(A), the filing of an ANDA can constitute an artificial act of infringement and provide a patent holder the ability to bring a patent infringement suit (if the suit otherwise satisfies Fed. R. Civ. P. 11). In this instance, the infringement lawsuit brought by AbbVie and Besins against Watson and Paddock in August 2003 occurred as a result of their ANDAs filed in May 2003. Thus, AbbVie's and Besins's cause of action arose *prior to* the issuance of the COC in December 2003. Accordingly, by statute, the COC was inapplicable in that litigation as a matter of law. As a result, AbbVie and Besins could not properly invoke the "corrected" patent claims in that litigation and, since the claims in the '894 patent as issued did not cover AndroGel or AB-rated generic versions of AndroGel, Watson's and Paddock's generic versions of AndroGel did not infringe claims 1-30 of the '894 patent.

141. Even if the COC were valid and effective for purposes of AbbVie's and Besins's suits against Watson and Paddock, the "corrected" claims (or the claims that depended from them) were invalid given the absence of any written description support for the later-claimed ranges of sodium hydroxide. Likewise, claims 31-42 were not infringed in light of the presence of water and sodium hydroxide in Watson's and Par/Paddock's products and the material effect of those ingredients on the basic and novel properties of the claimed invention. Moreover, AndroGel was in the prior art due to on sale and in public use activity, and therefore any claims that covered AndroGel or its use were necessarily invalid for those additional reasons.

142. Any claims covering AndroGel or its use were invalid under the "on sale" bar

based on a 1995 Supply Agreement. According to Unimed's 10-K filing on December 31, 1995, it had a "supply agreement[]" with "Besins for AndroGel" under which Unimed "purchases clinical supplies, and after approval by the FDA, finished drug products in accordance with the Company's specifications." As a result of the 1995 Supply Agreement, AndroGel and its use were prior art to the '894 patent, which was not filed until 2000. Accordingly, any claims covering AndroGel or its use were necessarily invalid under the "on sale" bar. In addition, the AndroGel formulation was obvious because its composition was disclosed expressly or inherently through two different sources that were publicly accessible more than a year before the patent was filed. The AndroGel placebo – *i.e.* the exact AndroGel composition except for the active ingredient testosterone – was used publicly no later than May 11, 1999. In addition, the concentration of testosterone was also prior art because Solvay published in 1998 that AndroGel was a "1% hydroalcoholic gel preparation of testosterone (T)." Accordingly, any claims covering AndroGel or its use were necessarily invalid as obvious, in part based upon the "public use" bar.

H. AbbVie Was Concerned that Watson and/or Par/Paddock Could Launch Generic AndroGel as Early as 2006 and Forecasted that a Generic Version of AndroGel Would Take 90% of Brand AndroGel Sales

143. AbbVie knew that Hatch-Waxman's automatic 30-month stay would protect AndroGel 1% from facing generic competition until early 2006, and had little incentive to settle before then.

144. On January 6, 2006, the 30-month stay on approval of Watson's ANDA for its generic AndroGel product expired.

145. In late January 2006, Defendant Watson received final approval from the FDA to market its AB-rated generic version of AndroGel, meaning that FDA had determined that Watson's generic AndroGel was as safe and effective as branded AndroGel. Watson was awarded

180 days of marketing exclusivity (an “exclusivity” that could not apply against a brand company’s own authorized generic) for being the first to file an ANDA containing a Paragraph IV certification.

146. The FDA tentatively approved Paddock’s ANDA on October 27, 2004, and finally approved it on May 23, 2007.

147. AbbVie was aware that once Watson received final FDA approval, Watson could launch its generic version of AndroGel unless AbbVie could satisfy the prerequisites for an injunction in the patent case to prevent Watson’s launch. But AbbVie knew that they would be unable to obtain an injunction against Watson (or Par/Paddock) because, *inter alia*, AbbVie would be unable to establish a likelihood of prevailing on the merits. Knowing they could not exclude Watson and Par/Paddock through any legal means, *i.e.*, a preliminary injunction, AbbVie considered ways to settle the patent litigation and eliminate the near-term threat of generic competition without risking a potential adverse court decision in the patent case. In late November 2005, Watson moved for partial summary judgment on patent invalidity against AbbVie and Besins in the patent litigation. By the end of January 2006, that motion was fully briefed.

148. In 2005, AbbVie undertook analyses to measure the impact of a mid-2006 entry of generic versions of AndroGel on AbbVie’s sales. Nine days after taking over as CEO of Solvay (a predecessor-in-interest of AbbVie, Inc.), Laurence Downey requested that his executive team develop a contingency plan showing the effect of AndroGel generic entry in the second quarter of 2006. In mid-2005, Solvay executives created an analysis predicting that Solvay would lose \$281 million of its \$311 million expected AndroGel sales in 2007 if it lost the AndroGel patent litigation. At that time, Solvay’s executive team discussed a possible at-risk launch of generic AndroGel, *i.e.*, a launch while the patent infringement litigation was still pending.

149. On January 30, 2006, AbbVie learned that Watson, the first-filer for generic AndroGel had received final FDA approval for its AndroGel ANDA. Watson no longer faced any regulatory hurdles to launch once it received final FDA approval.

I. Watson and Par/Paddock Were Preparing to Launch Generic AndroGel in 2006

150. After receiving final FDA approval of its ANDA on January 27, 2006, Watson took steps to prepare to manufacture and launch its generic version of AndroGel 1%. Between January 1 and September 13, 2006, Watson forecasted entering the market with generic AndroGel sachets on January 1, 2007, and entering the market with the AndroGel pump in 2007.

151. Likewise, after Paddock received tentative approval for its generic AndroGel product on October 27, 2004, its partner, Par, planned to enter the market as quickly as possible and forecasted expected entry dates beginning in September 2006. Paddock spent \$750,000 in equipment for development of generic AndroGel, and roughly \$3 million, excluding legal fees, to develop the product. In or around late 2005/early 2006, Paddock manufactured a batch of commercial-scale product for generic AndroGel. Paddock also conducted equipment testing on the packet filler to verify that the equipment was working properly. On a Q4 2005 earnings call with Par investors, Par's CEO Scott Tarriff indicated that if AndroGel did not come to market in 2006, it certainly would in 2007.

J. AbbVie Induced Watson and Par/Paddock to Give Up their Patent Fight and Stay off the Market until 2015 by Offering Them a Share of Branded AndroGel Profits

152. AbbVie anticipated losing approximately 90% of their AndroGel sales within a year of the launch of a generic version of AndroGel. AbbVie began analyzing whether it made financial sense to pay expected generic competitors Watson and Par/Paddock to stay out of the AndroGel

market for a lengthy period of time. To that end, Solvay put together a financial model to analyze the options, which included an evaluation of the net present value to Par and Watson of generic entry during different timeframes.

153. On April 6, 2006, Dr. Downey, the President and CEO of Solvay's U.S. operations, emailed other Solvay executives requesting a financial analysis to support Solvay's "best guess" proposals for Watson and Par stating "i.e., they detail Androgel . . . generic 2015... etc." (ellipses in original).

154. Solvay analyst Elaine (Difei) Yang was assigned to look simultaneously at the impact of the settlement of the AndroGel patent litigations, the negotiation of the co-promotion agreement with Watson, and the negotiation of the co-promotion agreement and back-up manufacturing and supply agreement with Par. This analysis was given the internal code name "Project Tulip," took place over the course of seven months, and generated numerous documents, presentations and analyses.

155. On April 9, 2006, Ms. Yang emailed a presentation that discussed an arrangement providing for a net present value (NPV) payment of \$57 million to Watson and \$32 million to Par for co-promotion services through 2014. The next day, Dr. Downey received a presentation regarding deal structures relating to Project Tulip which included a discussion of "Potential Settlement Features" for Watson and Par of a co-promotion in urology and/or HIV and a manufacturing agreement, as well as an agreement (as to Watson) not to launch an authorized generic.

156. A key April 24, 2006 Project Tulip presentation predicted the expected financial results from litigation in three scenarios: (1) AbbVie winning the patent litigation; (2) AbbVie losing the patent litigation; and (3) AbbVie having an assumed 50% chance of winning the patent

litigation. AbbVie concluded that if it prevailed in its patent suits against Watson and Par/Paddock, it expected to earn \$1.2 billion in profits from AndroGel; if it lost the litigation, it expected to earn far less. If AbbVie lost the litigation, the combined profits of AbbVie, Watson, and Par/Paddock would be far less than AbbVie could earn if AbbVie won, because generic competition would bring much lower prices.

157. AbbVie realized that they could easily afford to buy Watson's and Par/Paddock's agreement not to compete, thus eliminating the near-term threat of generic entry. By delaying competition, AbbVie, Watson, and Par/Paddock would preserve monopoly profits that could be shared amongst themselves at the expense of the purchaser savings that would have resulted from generic price competition. Thus, even after paying a share of their profits to Watson and Par/Paddock to secure their agreement to delay entry until 2015, AbbVie still expected to make more in AndroGel profits by delaying entry of generic AndroGel 1% until 2015 than by continuing to litigate.

158. AbbVie expected that they would need to compensate Watson and Par/Paddock in order to obtain their agreement not to launch generic AndroGel 1% until 2015.

1. AbbVie Agrees to Pay Watson a Large and Unjustified Payment To Give Up the Patent Fight and To Not Launch Generic AndroGel until 2015

159. On September 13, 2006, AbbVie and Watson executed three agreements: a Final Settlement and Release Agreement resolving the patent litigation; a patent License Agreement; and a Co-Promotion Agreement. All three agreements were signed by the same three corporate officers. All three agreements were governed by New York law.

160. In the Final Settlement and Release Agreement, Watson agreed not to launch its generic AndroGel product before August 31, 2015. Moreover, under the terms of the Settlement,

Watson agreed to “relinquish its claim to any 180-day market exclusivity it may be entitled to under 35 [sic] U.S.C. §355(j)(5)(B)(iv) with respect to ANDA No. 76-737.” (The settlement agreement was technically between Unimed Pharmaceuticals, Inc. and all its Affiliates, Laboratories Besins Iscovesco and all its Affiliates, and Watson Pharmaceuticals, Inc. and all its Affiliates). On the same day they settled the AndroGel patent litigation, AbbVie and Watson simultaneously entered into a co-promotion deal, which provided substantial compensation to Watson.

161. Under the terms of the Co-Promotion Agreement, AbbVie agreed to provide Watson with a majority share of AbbVie’s profits from AndroGel prescriptions written by urologists – starting at 60% in 2006 and ultimately increasing to 70% regardless of Watson’s co-promotion efforts contributing to those sales. (The Co-Promotion Agreement was technically between Solvay Pharmaceuticals, Inc. on behalf of Unimed Pharmaceuticals, Inc., and Watson Pharma, Inc.).

162. AbbVie, Besins and Watson filed a voluntary stipulation of dismissal terminating their patent litigation in the district court. The parties did not file their settlement and co-promotion agreements with the court, nor were the agreements contingent on court approval.

163. The Watson Co-Promotion Agreement ran consecutively with Watson’s agreement to stay out of the AndroGel market and expired shortly after Watson’s licensed entry date for generic AndroGel.

164. Watson and its successor, Actavis, Inc. (n/k/a Allergan Finance, LLC), adhered to its unlawful agreement to delay generic competition and did not begin selling generic AndroGel in the United States until November 2015. Unimed, Solvay and their successors-in-interest also adhered to the unlawful agreement.

165. From 2006 through 2015, AbbVie paid Watson and its successor Actavis, Inc. (n/k/a Allergan Finance, LLC) more than \$341 million pursuant to the Co-Promotion Agreement.

166. AbbVie's payments to Watson and its successor Actavis, Inc. far exceeded any reasonable estimate of saved or avoided litigation costs from settling the patent litigation. Based on the 2011 biannual survey of the American Intellectual Property Lawyers Association, the median total litigation costs for patent infringement cases involving more than \$25 million at risk in 2007 was \$5 million, of which \$3 million was expended during discovery. Therefore, median litigation costs for such cases from the end of discovery to the end of the case were \$2 million.

2. The Watson Co-Promotion Deal Was Pretextual

167. Watson was only willing to delay its generic entry to 2015 if it received compensation for that delay, in this case under the pretextual "co-promotion" agreement. The amount of AbbVie's payment to Watson also had to be substantial enough to compensate Watson for the risk posed to Watson by AbbVie's planned new version of AndroGel that threatened to destroy the market for AndroGel 1% and thereby make Watson's generic AndroGel 1% product far less valuable by reducing the base of branded AndroGel 1% prescriptions available for automatic substitution with a generic.

168. Watson proposed that AbbVie share AndroGel revenues with Watson through an arrangement under which Watson would co-promote AndroGel to doctors. Just months before, however, a consulting firm had helped Solvay conduct a comprehensive analysis of Solvay's AndroGel promotion options. That analysis concluded that AndroGel co-promotion was not appropriate for Solvay, and in any event, Watson did not meet the set of criteria for potential co-promotion partners discussed in that analysis. Yet, because Solvay wanted to protect its AndroGel revenues for another nine years (until 2015), Solvay quickly agreed to consider allocating a portion

of AndroGel sales to Watson for supposed “co-promotion” services.

169. Before the parties entered into the Watson Co-Promotion Agreement, Solvay had entered two other co-promotion agreements for AndroGel with TAP Pharmaceutical Products, Inc. (“TAP”) and ICOS Corporation (“ICOS”). The TAP and ICOS co-promotion agreements both involved these companies promoting AndroGel to urologists and other types of doctors. Both agreements were unsuccessful, however, and terminated early.

170. Despite the fact that AbbVie had no reason to enter another co-promotion arrangement, AbbVie and Watson began discussing settling the patent litigation by entering into a business arrangement such as a co-promotion agreement.

171. On April 20, 2006, Watson’s General Counsel and other senior executives met with Solvay’s CEO, General Counsel and other senior executives. During their meeting, they discussed settlement of the patent litigation, including specific dates for Watson’s AndroGel generic entry, and the possibility of entering into a co-promotion agreement for AndroGel.

172. AbbVie and Watson executives met again on April 27, 2006, the day after Solvay’s critical Project Tulip analysis was created. They discussed settlement of the patent litigation in conjunction with entering a co-promotion agreement. They “agreed in principle that the generic AndroGel entry date would be 2015” and that they “had basic agreement on the structure of the settlement and then the additional details would be worked out after that.”

173. On April 28, 2006, Solvay’s General Counsel emailed to Watson executives a PowerPoint presentation, which included proposed preliminary terms of a Solvay/Watson co-promotion deal for Watson to co-promote AndroGel to urologists. The presentation was labeled “[f]or purposes of settlement negotiations only” thus explicitly linking it to the AndroGel patent

litigation settlement negotiations. It also included a “Profit Sharing Schedule,” which appears to have formed the basis of the profit split numbers in the final Watson Co-Promotion agreement.

174. In the Watson Co-Promotion Agreement, AbbVie agreed to pay Watson 60% of its AndroGel urology net profits from the fourth quarter of 2006 even though Watson would not begin promoting AndroGel to urologists until early 2007.

175. Before entering previous co-promotion agreements with other entities – TAP and ICOS – Solvay conducted detailed evaluations to assess whether those companies were a good fit to co-promote AndroGel and whether those arrangements made financial sense. Before entering into the Watson Co-Promotion Agreement, Solvay did not conduct any such evaluation of whether the co-promotion would achieve financial benefits or whether Watson was a good fit to co-promote AndroGel.

176. Also unlike the TAP and ICOS co-promotion agreements, which were limited to 2.5 and 2 years respectively, the Watson Co-Promotion Agreement had an unusually long, nine-year term.

177. Co-promotion deals commonly determine the co-promoter’s compensation by comparing sales from the co-promotion to a baseline of pre-existing sales. Solvay’s agreements with TAP and ICOS did so and allowed for termination if AndroGel sales did not reach a certain level. The Watson Co-Promotion Agreement required Solvay to make guaranteed annual payments to Watson based on Solvay’s total annual AndroGel sales and did not include a baseline. Although Solvay included a termination provision in its earlier ICOS and TAP co-promotion agreements, Solvay could not terminate the Watson agreement based on lower than expected sales.

3. The Watson Co-Promotion Agreement Was a Market Allocation Agreement Between Horizontal Competitors

178. Through the terms of the Settlement, Licensing, and Co-Promotion Agreements between AbbVie and Watson, Watson – once a would-be competitor who was seeking to market a lower-priced generic AndroGel as soon as possible – ceded the entire AndroGel market to AbbVie in exchange for a share of the branded AndroGel profits until 2015.

179. The Co-Promotion Agreement between AbbVie and Watson was timed to expire at the time that generic entry would occur under the Settlement and Patent License Agreements – *i.e.* on August 31, 2015.

180. The Watson Co-Promotion Agreement further provided that “SOLVAY shall compensate WATSON” with “the percentage of AndroGel Net Profits” as shown in a schedule, which gives Watson 60% of Solvay’s AndroGel Net Profits (defined in the Co-Promotion Agreement as a percentage of Urology prescriptions) in 2006, increasing to 70% by 2012, and then holding this 70-30 split until 2015.

181. From 2006 until after generic entry in 2015, AbbVie agreed to provide Watson with a majority share of the profits from branded AndroGel prescriptions written by urologists regardless of Watson’s co-promotion efforts contributing to those sales.

182. Under the Watson Co-Promotion Agreement, AbbVie agreed to pay Watson 60% of AndroGel Net Profits in Urology that Solvay earned in the fourth quarter of 2006 – even though Watson did not begin detailing AndroGel until early 2007 and had no obligation to begin any earlier.

183. Watson personnel commented that its negotiators “negotiated a much better deal for Watson” because they “cleverly insisted we wanted to be ‘joint owners’ of the Urology Market Segment for AndroGel and in fact Watson starts out ‘owning’ more than Solvay and our ownership

goes up over time.”

4. AbbVie Agreed To Pay Par/Paddock a Large and Unjustified Payment Not To Launch Generic AndroGel Until 2015

184. Par/Paddock, like Watson, was willing to delay its entry until at least August 2015 only if it received compensation for that delay. In the words of a senior Par executive, Par was looking to “extract payments” from AbbVie in settlement negotiations.

185. On September 13, 2006, the same day that AbbVie signed agreements with Watson, Solvay signed four agreements with Par/Paddock; the Final Settlement and Release Agreement, the Patent License Agreement, the Co-Promotion Agreement, and the Back-up Manufacturing Agreement. All of these agreements were signed by the same individuals.

186. Under the Final Settlement and Release Agreement, Par/Paddock agreed that they would not sell generic AndroGel until at the earliest August 31, 2015. (The agreement was technically between Unimed Pharmaceuticals and all its Affiliates, Laboratories Besins Iscovesco and all its Affiliates, Par Pharmaceutical Companies, Inc. and all its Affiliates, and Paddock Laboratories, Inc. and all its Affiliates). Par/Paddock and their successors adhered to this agreement. Unimed and Besins and their respective successors-in-interest also adhered to the agreement.

187. Under the Par Co-Promotion Agreement, AbbVie agreed to pay Par \$10 million a year for six years – a total of \$60 million. (The Co-Promotion Agreement is technically between Solvay Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc). Solvay, Unimed and Par and their respective successors-in-interest adhered to the co-promotion agreement until it was terminated effective January 1, 2011.

188. Under the Backup Manufacturing Agreement, AbbVie agreed to pay Par or its

designee \$2 million a year for six years – a total of \$12 million “irrespective of whether Par or its Designee shall ever be called upon to Manufacture Product hereunder.” Paddock served as Par’s designee to manufacture and supply AndroGel. (The Backup Manufacturing Agreement is technically between Unimed Pharmaceuticals, Inc. and its Affiliates, Laboratoires Besins International S.A. and its Affiliates, and Par Pharmaceutical Companies, Inc. and its Affiliate, Par Pharmaceutical, Inc.). Unimed, Besins and Par and their respective successors-in-interest adhered to the Backup Manufacturing Agreement.

189. The compensation AbbVie agreed to provide Par and Paddock was designed to, and did, induce Par and Paddock to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2015. Rather than compete, AbbVie and Par/Paddock agreed to share in the monopoly profits of branded AndroGel.

190. AbbVie and Par/Paddock drafted a proposed consent judgment to dismiss the infringement suit against Paddock, and requested that the district court hearing the patent litigation enter it. AbbVie and Par/Paddock did not file their settlement, co-promotion and back-up manufacturing agreements with the court, nor were the agreements contingent upon court approval.

191. At the time the Par/Paddock Co-Promotion and Backup Manufacturing Agreements were negotiated, AbbVie expected to pay Par/Paddock \$72 million over the life of those agreements.

192. AbbVie actually paid Par/Paddock approximately \$44.5 million under the Par Co-promotion Agreement and \$12 million under the Backup Manufacturing Agreement. *See also FTC v. Actavis, Inc.*, 570 U.S. 136, 145 (2013) (“Solvay agreed to pay millions of dollars to each generic – \$12 million in total to Paddock; \$60 million in total to Par; and an estimated \$19-30

million annually, for nine years, to Actavis.”) (citing FTC’s complaint and holding that the FTC’s allegations stated an antitrust claim).

193. AbbVie’s payments to Par/Paddock far exceeded a reasonable estimate of AbbVie’s saved or avoided litigation costs from settling the patent litigation.

194. Par/Paddock did not begin selling generic AndroGel 1% in the United States until September 2015.

5. AbbVie’s Agreements With Par/Paddock Were Pretextual

195. On February 24, 2006, Paul Campanelli, the President and CEO of Par sent an email to another Par executive that stated: “I am going to be at Solvay in a couple of hours to have an introductory meeting regarding a very preliminary meeting on AndroGel Settlement. I am looking for value. Do you see anything we can do for them where we can extract payments for [sic] them on the brand side? Marinol? I know it probably works against Megace. Co promote anything?”

196. On April 28, 2006, after reaching an agreement in principle with Watson, AbbVie offered Par/Paddock entry in 2015, which Par executives accepted. On that same date, Par executive Paul Campanelli sent an email to Par employees that stated: “Please block out from 11 to 12 noon on Wednesday for a call with Solvay’s finance group in order to potentially settle AndroGel . . . The purpose for this teleconference is to attempt to agree on a value. I proqposed [sic] 28M per year. Needless to say they believe the number is considerably less.” Solvay and Par executed a Nondisclosure Agreement concerning negotiations related to settlement of the patent litigation between them.

197. In May 2006, Solvay and Par executives created and exchanged a series of financial analyses concerning the NPV of first and second filing generic AndroGel entrants assuming 2007

generic entry. Solvay and Par exchanged various spreadsheets and correspondence regarding the amount of money that Par should be paid for a manufacturing or co-promotion deal as a second filer. Based on the discounted value of Par's forecasted profits from selling generic AndroGel from 2007 through 2016 – which Par would forego in a settlement – Solvay and Par were able to agree on a value that Par would receive in exchange for settling the litigation and dropping its challenge to the '894 patent. Solvay and Par agreed on the payments Par would receive before agreeing on what Par would do in exchange, other than defer generic entry until 2015.

198. On May 9, 2006, Ed Maloney, Paddock's Vice President of Operations and Business Development, emailed Mr. Campanelli stating that Paddock wanted "a deal that paid Paddock \$6MM cash and also allowed for contract manufacture of the gel at a level of \$2MM gross profit per year at 50% gross margin ... or \$4MM in total revenue." Mr. Maloney also stated that "the [AndroGel] patent simply cannot be valid." He concluded the email by threatening: "Tell Lauri [Downey] that Paddock is trying to mess this up and see what happens." Mr. Maloney testified that he wanted to use his leverage with respect to refusing to agree to the settlement to get "a larger amount of money than would typically be paid." Mr. Campanelli replied to Mr. Maloney's email by saying that "[w]e can't indicate to Solvay that Paddock is trying to 'mess this up' – then we don't look united. We need to be very much aligned and expedite a potential settlement."

199. Even though Mr. Maloney testified that there was never another situation where Paddock allowed another company to negotiate on its behalf, no Paddock representative was directly involved in the negotiation of the Backup Manufacturing Agreement.

200. By May 11, 2006, Solvay and Par reached agreement that Solvay would pay Par \$12 million per year for six or seven years or \$72 million total in exchange for Par's generic entry

to occur 180 days after Watson entered in Q4 2015. Former Solvay Executive Vice President and Chief Financial Officer Murray Kay testified that he and Par “agreed to . . . a business arrangement whereby Par would receive consideration of 12 million per year for six years. The possibilities explored include manufacturing, development and/or a co-promotion between Par and Solvay.” On May 12, 2006, Mr. Kay emailed Mr. Campanelli saying “this note confirms our agreed-upon settlement of \$12 million per year for 6 years coupled with manufacturing/development and/or a co-promotion between Par and Solvay. Jim and I will be meeting with you and John on May 25th to discuss the specifics.” Mr. Campanelli wrote back to “confirm agreement.” On that date, Mr. Kay also sent Dr. Downey a presentation entitled “Tulip May 2006.ppt” which depicted annual payments to Par of \$12 million for “Manufacturing and/or Co-Promotion” in 2007-2010.

201. On May 19, 2006, Ms. Yang emailed Mr. Kay: “I am trying to look at if it is possible at all to pay \$12 MUSD all in manufacturing arrangement which would be the cleanest arrangement.” In an email later that day, after receiving additional information, Ms. Yang wrote “it is clear that unless we move all volumes or at least majority of AndroGel volume over to Paddock, we cannot come up with \$12 MUSD with manufacturing arrangement alone For the time being, I will leave the manufacturing piece aside and see if we can make any other arrangement.”

202. A Solvay memorandum prepared for a May 25, 2006 meeting indicated that Par would be allowed to launch generic AndroGel in the second quarter of 2016 and that Par would receive “12 MUSD for 6 years in exchange for providing the following services for example: Manufacturing/Development/Backup Manufacturing – AndroGel and/or Co-promotion leveraging Par’s sales force: Luvox CR (Psychiatry)[;] AndroGel (Extended Reach)[;] Marinol (Oncology).” The document also contained a “Manufacturing Options” slide that considered several

manufacturing and development services Par or Paddock could provide.

203. Thus, only after they agreed upon the compensation and generic entry date did Solvay and Par agree to meet to “discuss the form of consideration” and whether it would be for “manufacturing/development/backup and co-promotion.” After the parties agreed on the amount that Solvay would pay Par, the parties met to discuss what type of business arrangement would accompany the settlement and how they would allocate the earlier agreed-upon payments. The parties decided that Par would co-promote AndroGel to doctors and receive \$10 million annually, and Paddock would serve as back-up manufacturer for AndroGel and receive \$2 million annually. As a Besins executive admitted in an email, the “backup manufacturer strategy [was] a partial way to compensate Parr [sic] for **not entering the market.**” (emphasis added).

K. The Par Co-Promotion Agreement and Par/Paddock Back-Up Manufacturing Agreement Were Market Allocation Agreements Between Horizontal Competitors

204. Through the terms of the Settlement, Licensing, Co-Promotion and Back-Up Manufacturing Agreements between AbbVie, Besins, and Par/Paddock, Par/Paddock ceded the entire AndroGel market to AbbVie until 2015 in exchange for a share of branded AndroGel profits.

205. Through the Par Co-Promotion Agreement, AbbVie agreed to share profits of AndroGel with Par, and Par agreed to promote AndroGel to primary care physicians and others. AbbVie agreed to pay Par \$2.5 million per quarter for six years beginning the fourth quarter of 2006.

206. Through the Par/Paddock Back-Up Manufacturing Agreement, AbbVie committed to share profits of AndroGel with Par/Paddock, and Par designated Paddock to serve as a backup supplier of AndroGel. AbbVie and Besins agreed to pay Par/Paddock \$500,000 per quarter beginning in October 2006 until September 2012 regardless of whether Par/Paddock actually

manufactured any product for AbbVie.

207. Despite Par/Paddock's prior position in the patent litigation brought by AbbVie and Besins, after entering the Co-Promotion and Back-Up Manufacturing Agreements in September 2006, Par/Paddock jointly drafted a Consent Judgment and Order of Permanent Injunction with AbbVie, under which Par/Paddock "acknowledge[d] that the claims of the '894 Patent are valid and enforceable in all respects," and that the sale of Par/Paddock's proposed product "would infringe the claims of the '894 Patent, as asserted in the Complaint against Paddock" and which enjoined Par/Paddock from commercially marketing its generic AndroGel until August 31, 2015.

208. When submitting the Consent Judgment and Order of Permanent Injunction to the Court, neither Par/Paddock nor AbbVie informed the Court that business agreements valued at tens of millions of dollars were linked to the settlement.

L. AbbVie Used the Delay Purchased through the Watson and Par/Paddock Agreements to Shift the Market to a New, Non-AB-Rated AndroGel 1.62% Product

209. AbbVie's multi-million dollar payments to Watson and Par/Paddock compensated them for agreeing to delay their market entry until at the earliest August 31, 2015. AbbVie knew that they would reap excess profits during that period of unlawful delay. AbbVie's anticompetitive agreements with Watson and Par/Paddock, therefore, were in each of their financial interests, but harmed Plaintiffs who directly purchased AndroGel 1% and 1.62%, by causing Plaintiffs to be overcharged. The delay in generic competition also harmed consumers, competition, and consumer welfare.

210. AbbVie used the nearly ten-year period of generic delay to develop and market a more concentrated version of AndroGel 1% called AndroGel 1.62%, that was basically the same as AndroGel 1% except it allowed patients to use less gel volume. AbbVie switched sales from

AndroGel 1% to AndroGel 1.62% before the end of 2014 so that when generic versions of AndroGel 1% finally launched, they would not be automatically substituted for prescriptions for AndroGel 1.62%, and therefore AbbVie would be able to continue to charge supra-competitive prices for AndroGel 1.62% and nevertheless retain those sales. The product switch or “hop” from branded AndroGel 1% to 1.62% also suppressed sales of generic AndroGel 1%. An AB-rated generic can be automatically substituted by pharmacies for the brand in filling prescriptions for the brand, but this automatic substitution applies only to the brand for which the generic is AB-rated. Hence, the lower the brand prescription volume at the time of generic entry, the lower the generic sales. That is the whole point of a brand engaging in a product switch.

M. Two New Generic Competitors Threatened AbbVie’s AndroGel Franchise

211. A few years after AbbVie paid Watson and Par/Paddock to delay their generic entry in 2006 and before AbbVie shifted the market to AndroGel 1.62%, AbbVie faced a new threat to their lucrative AndroGel franchise from additional potential generic competitors, this time Perrigo and Teva.

212. After the ‘894 patent issued, both Perrigo and Teva (along with its development partner BioSante Pharmaceuticals) developed testosterone gel products that would not infringe the ‘894 patent because, *inter alia*, they did not use the penetration enhancer required by each of the claims in the ‘894 patent.

213. Perrigo developed a testosterone gel formulation containing ISA rather than IPM, the penetration enhancer required by each of the claims of the ‘894 patent. Any argument by AbbVie that the claims of the ‘894 patent covered the Perrigo formulation or its use was objectively and subjectively baseless.

214. Teva and BioSante developed a testosterone gel formulation containing IPP rather

than IPM, the penetration enhancer required by the claims of the '894 patent. Any argument by AbbVie that the claims of the '894 patent covered the Teva formulation or its use was objectively and subjectively baseless.

N. In 2009, AbbVie Decided Not To File An Infringement Suit Against Perrigo

215. In December 2008, Perrigo submitted to the FDA two generic applications seeking approval to market generic AndroGel in both pump and packet form. In June 2009, Perrigo sent AbbVie and Besins a paragraph IV notice letter explaining that Perrigo's product did not literally infringe the '894 patent because it did not contain IPM, the penetration enhancer required by the patent claims. Perrigo also stated in its notice that the prosecution history of the '894 patent would estop AbbVie and Besins from establishing infringement under the doctrine of equivalents. Finally, Perrigo offered to provide to outside counsel representing AbbVie and Besins confidential access to the full ANDAs.

216. In response to Perrigo's paragraph IV notice letter, AbbVie and Besins retained patent counsel to review potential bases for a patent infringement lawsuit against Perrigo.

217. Following patent counsel's review, AbbVie and Besins confirmed that Perrigo's generic product as specified in its generic application did not contain IPM. AbbVie decided not to file a patent infringement suit against Perrigo. In a July 2009 press release announcing the decision not to sue, Solvay noted that, unlike earlier generic AndroGel products, Perrigo's product "contains a different formulation than the formulation protected by the AndroGel patent" and stated that "[t]his distinction played a role in the company's decision not to file patent infringement litigation at this time." Besins also determined that it was "standing down" from bringing an infringement suit but did not join in the Solvay press release or issue its own public announcement.

218. Solvay prepared an internal document to coordinate the communication strategy

regarding its decision not to sue Perrigo. This document included prepared responses to various potential questions, including:

Why didn't you initiate a patent infringement suit against Perrigo?

. . . We conducted a thorough analysis based upon the contents of the Paragraph IV certifications and the information available to us, determined there was not a sufficient basis for filing patent infringement litigation at this time.

. . . .

Why not commence patent litigation to trigger the 30-month stay of approval? Solvay Pharmaceuticals takes it [*sic*] obligations under U.S. law very seriously. These obligations include certain pleading requirements that must be satisfied prior to initiating any litigation, including patent infringement litigation.

O. AbbVie Filed A Citizen Petition With The FDA, Causing Perrigo And Teva To Seek Approval Of Their Products Through 505(b)(2) Applications

219. Without a 30-month stay of FDA approval in place to forestall Perrigo's market entry, AbbVie explored other avenues to prevent or limit generic competition.

220. On April 9, 2010, AbbVie Inc.'s predecessor, Abbott, submitted a citizen petition to the FDA related to Perrigo's generic application. Abbott asked the FDA to require Perrigo, or any other firm seeking approval for a generic AndroGel product utilizing a penetration enhancer other than IPM, to conduct additional safety studies and file an NDA rather than an ANDA. According to Abbott, generic versions of topical drugs containing different inactive ingredients than the brand-name drug pose "unique scientific challenges" and the FDA could not approve "any pending ANDA for a product containing a different penetration enhancer than AndroGel."

221. The FDA granted Abbott's petition in part on October 4, 2010, stating that specified safety studies would be required for "[testosterone gel] products with penetration enhancers that differ from those used in the [brand-name drug]." The practical effect of this ruling was that

Perrigo (and later Teva) had to submit a 505(b)(2) application instead of a 505(j) ANDA and re-certify that its product did not infringe the '894 patent.

222. Teva and Perrigo performed the required safety studies and submitted 505(b)(2) applications to the FDA in January 2011 and July 2011, respectively. The testosterone gel products that were the subject of these 505(b)(2) applications contained penetration enhancers other than IPM, the penetration enhancer required by each of the claims of the '894 patent. The formulation for Perrigo's 505(b)(2) product was almost identical to the formulation for Perrigo's ANDA product—both included ISA as a penetration enhancer.

P. AbbVie and Besins Filed Sham Patent Litigation Against Teva And Perrigo To Delay Approval Of Their Generic Applications For Up To 30 Months

223. AbbVie maintained their market and monopoly power in the United States with respect to AndroGel by filing sham lawsuits against potential competitors Teva and Perrigo.

224. On March 16, 2011, Teva sent AbbVie and Besins a Paragraph IV notice letter stating that Teva had submitted NDA No. 202763 (a 505(b)(2) application) to the FDA seeking approval to sell generic AndroGel. The letter also stated that Teva's 505(b)(2) application contained a Paragraph IV certification that Teva's product did not infringe the '894 patent. Teva provided AbbVie and Besins with an Offer of Confidential Access to Application that allowed them to review Teva's 505(b)(2) application to confirm that Teva's proposed product did not contain IPM.

225. AbbVie and Besins or their representatives received confidential access to parts of Teva's 505(b)(2) NDA. As a result, AbbVie and Besins or their representatives learned that the penetration enhancer in Teva's product was not IPM, but rather a different penetration enhancer, IPP.

226. On April 29, 2011, AbbVie and Besins nevertheless filed a patent infringement lawsuit against Teva in the U.S. District Court for the District of Delaware (captioned *Abbott Products, Inc. v. Teva Pharmaceuticals*, No. 1:11-cv-00384-HB). The filing of the lawsuit automatically triggered a 30-month stay of FDA approval of Teva's testosterone gel product.

227. AbbVie and Besins have not asserted that Teva's product literally infringes the '894 patent because the product does not contain IPM, the penetration enhancer required by each of the claims in the patent. Rather, AbbVie and Besins asserted that Teva's product infringes the patent under the doctrine of equivalents because Teva's penetration enhancer IPP is allegedly equivalent to, and insubstantially different from, IPM.

228. In response to the AbbVie/Besins complaint, Teva filed antitrust counterclaims. In its counterclaims, Teva asserted that the infringement claims were baseless and a sham because during prosecution of the '894 patent, AbbVie and Besins had surrendered patent claims that would have covered a testosterone gel containing IPP. According to Teva, AbbVie and Besins were therefore plainly precluded under the doctrine of prosecution history estoppel from asserting infringement under the doctrine of equivalents.

229. On August 1, 2011, Teva filed a motion for summary judgment on the issue of prosecution history estoppel. On October 25, 2011, the district court denied that motion as moot because it had scheduled a trial limited to the estoppel issue. The trial was scheduled to begin May 21, 2012, just 13 months after AbbVie and Besins had filed their complaint.

230. The FDA granted final approval to Teva's (sachet) product on February 14, 2012, and assigned a BX rating to Teva's product on July 23, 2014.

Q. AbbVie and Besins Sued Perrigo Even Though Perrigo's Product Does Not Contain IPM

231. On July 4, 2011, Perrigo re-filed with the FDA its application for approval of a generic testosterone 1% gel as a 505(b)(2) NDA. On September 20, 2011, Perrigo sent AbbVie and Besins a paragraph IV notice letter stating that Perrigo had submitted NDA No. 203098 (its 505(b)(2) application) to the FDA for a testosterone gel product. The letter also stated that Perrigo's application contained a Paragraph IV certification that Perrigo's product did not infringe the '894 patent because it did not contain IPM. In its letter, Perrigo made clear its view that any patent infringement suit against Perrigo in connection with Perrigo's 505(b)(2) application would be "objectively baseless and a sham," particularly in light of AbbVie's prior decision not to sue Perrigo due to the differences between Perrigo's formulation and the patented formulation. Perrigo further asserted that "a bad faith motive for bringing such a suit would be particularly apparent in light of representations and admissions made, *inter alia*, in [Solvay's] Friday, July 17, 2009 press release." Perrigo offered confidential access to certain information regarding the 505(b)(2) NDA to confirm that Perrigo's proposed product did not contain IPM.

232. AbbVie or their representatives received confidential access to parts of Perrigo's 505(b)(2) NDA. As a result, AbbVie or their representatives learned that – as in Perrigo's earlier generic AndroGel ANDA product – the penetration enhancer in Perrigo's 505(b)(2) NDA product was not IPM, but rather a different penetration enhancer, ISA. Besins or its representatives also evaluated Perrigo's NDA.

233. On October 31, 2011, AbbVie and Besins nevertheless filed a patent infringement lawsuit against Perrigo in the U.S. District Court for the District of New Jersey (captioned *Abbott Products, Inc. v. Perrigo Company*, No. 3:11-cv-06357-FLW-LHG). The filing of the lawsuit

automatically triggered a 30-month stay of FDA approval of Perrigo's product.

234. AbbVie and Besins have not asserted that Perrigo's product literally infringes the '894 patent because the product does not contain IPM, the penetration enhancer claimed in the '894 patent. Rather, they assert that Perrigo's product infringes the patent under the doctrine of equivalents because Perrigo's penetration enhancer ISA is allegedly equivalent to, and insubstantially different from, IPM.

235. The FDA granted approval to Perrigo's product on January 31, 2013. The FDA assigned an AB rating to Perrigo's product on July 23, 2014, after Perrigo had filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia on March 21, 2014, for failing to make a timely decision on the therapeutic equivalence rating for Perrigo's product. As Judge Bartle found following a three-week bench trial, absent AbbVie's and Besins's sham patent litigation, Perrigo would have received a ruling on therapeutic equivalence in June 2013 and launched an AB-rated generic AndroGel around that time.

R. AbbVie's and Besins's Lawsuits Against Teva And Perrigo Were Shams

236. As Judge Bartle found, AbbVie's and Besins's lawsuits against Teva and Perrigo were without question objectively baseless. Teva's and Perrigo's products are well outside the scope of the '894 patent under any theory of infringement.

237. The law with respect to sham litigation, the doctrine of equivalents, and prosecution history estoppel was well-settled at the time that AbbVie and Besins filed their lawsuits against Teva and Perrigo in 2011.

238. The lawsuits against Teva and Perrigo were objectively baseless in light of the doctrines of prosecution history estoppel and public dedication. The doctrine of prosecution history

estoppel with certain exceptions precludes a patentee from claiming equivalents if the patentee surrendered the equivalents for reasons relating to patentability during the patent prosecution process. Under the public dedication doctrine, a patent owner cannot cover, under the doctrine of equivalents, subject matter that was disclosed in the patent application but unclaimed (*i.e.*, in this case, the penetration enhancers employed in the Teva and Perrigo products).

239. The purpose of prosecution history estoppel is to protect the patentee's competitors from patent infringement litigation based on the doctrine of equivalents if the prosecution history demonstrates that the alleged equivalent at issue was surrendered during prosecution. When a narrowing claim amendment is involved, the patentee has the burden to overcome the presumption of surrender. Here, any reasonable person who reads the prosecution history of the '894 patent can reach no other conclusion than that AbbVie and Besins have purposefully (and not tangentially) excluded ISA and IPP as penetration enhancers equivalent to IPM.

240. Neither Teva's nor Perrigo's product literally infringes the '894 patent. Each independent claim of the '894 patent covers only a testosterone gel formulation (or use of such a formulation) that contains IPM. Neither Teva's product nor Perrigo's product contains IPM. AbbVie and Besins have not asserted that Teva's and Perrigo's products literally infringe the '894 patent.

241. Neither Teva's nor Perrigo's product infringes the '894 patent under the doctrine of equivalents. AbbVie and Besins have asserted that the penetration enhancers used in Teva's and Perrigo's products (IPP and ISA, respectively) are equivalent to and insubstantially different from IPM; however, the doctrines of prosecution history estoppel and public dedication preclude AbbVie and Besins from successfully advancing this theory of infringement. With regard to the former, the examiner in June 2001 rejected claim 1, which claimed all penetration enhancers. In

light of this rejection, over the course of their October 2001, December 2001, and February 2002 amendments, AbbVie and Besins without question narrowed the claimed penetration enhancers in the '777 application from all penetration enhancers including those used in the Teva and Perrigo products to only IPM at particular concentrations. This narrowing of claims was necessary for AbbVie and Besins to distinguish their claimed formulation from the prior art and to obtain a patent.

242. Both Teva's and Perrigo's penetration enhancers were plainly foreseeable at the time AbbVie and Besins amended their claims during prosecution of the '894 patent application. Teva's penetration enhancer was specifically identified in the prior art cited by the patent examiner in the June 2001 office action rejecting all pending claims under consideration, included in a small group of compounds described in the '894 patent specification, and included in the scope of the patent claims contained in AbbVie's and Besins's original patent application. Perrigo's penetration enhancer was known in the prior art, specifically listed in the '894 patent specification, and specifically listed as one of 24 compounds (or classes of compounds) recited in the October 19, 2001 amendment to AbbVie's and Besins's patent claims.

243. The amendments narrowing AbbVie's and Besins's patent claims from a group of penetration enhancers to the single penetration enhancer IPM were not tangential to the alleged equivalents. The patent prosecution history clearly indicates that the patent examiner viewed the claims as obvious over the prior art, which disclosed both the use of various penetration enhancers in pharmaceutical products and the delivery of testosterone through the skin. As a result of the patent examiner's review of the prior art, AbbVie and Besins were forced to limit their patent claims to the use of the penetration enhancer IPM only.

244. The October 2001 amendment sought to overcome the rejection by narrowing the

original claim 1 for all penetration enhancers to only twenty-four. It thereby excluded IPP and countless other penetration enhancers previously rejected. If AbbVie and Besins merely sought to relinquish only certain penetration enhancers in October 2001, they easily could have said so.

245. In the December 2001 amendment, AbbVie and Besins disavowed twenty-three of the penetration enhancers listed in the October 2001 amendment, including ISA, when they narrowed the claimed penetration enhancer to IPM.

246. Given that IPP (the penetration enhancer in Teva's product) and ISA (the penetration enhancer in Perrigo's product) were known as available technologies at the time AbbVie and Besins filed for a patent, AbbVie and Besins had an obligation to claim the technologies if they wanted to later assert exclusive rights to their use in a testosterone gel. Where a patent applicant discloses but does not claim subject matter, the subject matter is dedicated to the public.

247. No reasonable litigant, having had access to the confidential information Teva and Perrigo provided to AbbVie and Besins, could reasonably have expected to prevail on the merits of a claim that either Teva's product or Perrigo's product infringes the '894 patent. AbbVie and Besins thus had no probable cause for initiating the lawsuits.

248. AbbVie and Besins commenced the lawsuits against Teva and Perrigo with the subjective and wrongful intent to interfere directly with the business relationships of Teva and Perrigo. AbbVie and Besins filed the lawsuits not to obtain a favorable outcome on the merits of the claims asserted but to achieve an anticompetitive objective and maintain their monopoly through the improper use of judicial process.

249. AbbVie and Besins knew when they filed their lawsuits that the mere filing of the

complaints would trigger automatic 30-month stays of FDA approval of Teva's and Perrigo's respective 505(b)(2) applications, and that they would get the benefit of the stays despite the lack of any reasonable basis for asserting that Teva's or Perrigo's product infringes the '894 patent. Even with no realistic chance of winning the lawsuits, the 30-month stays were of tremendous value to AbbVie and Besins because they blocked entry of Teva's and Perrigo's products and gave AbbVie and Besins time to shift or "hop" sales away from AndroGel 1% to AndroGel 1.62%.

250. The attorneys who decided to sue Teva and Perrigo for alleged patent infringement on behalf of AbbVie and Besins were aware of Teva and Perrigo's Paragraph IV certifications in which Teva and Perrigo declared that their products did not contain IPM as a penetration enhancer at all, much less in the particular concentrations claimed in the '894 patent. Outside counsel for AbbVie and Besins had confidential access to the section 505(b)(2) applications of Teva and Perrigo, which identified the penetration enhancers used by Teva and Perrigo. Both Paragraph IV notices called to the attention of AbbVie's and Besins's decision-makers that any infringement theory under the doctrine of equivalents would be barred by prosecution history estoppel. Perrigo even asserted that any infringement suit against it would be a sham.

251. AbbVie and Besins decision-makers knew in 2011 when they filed suit that Teva and Perrigo used penetration enhancers for their generic products which were distinctly different from the one penetration enhancer claimed in the '894 patent. The decision-makers also were aware of the prosecution history of the '894 patent and specifically that the patent application originally claimed all penetration enhancers including those in the Teva and Perrigo products, but that the penetration enhancers used by Teva and Perrigo were ultimately surrendered and excluded from the protection of the '894 patent. The prosecution history detailed that the original claims covered all penetration enhancers but ultimately were narrowed to one, IPM.

252. AbbVie's patent attorneys, some of whom were long-time in-house counsel, were generally aware of the extensive financial success of AndroGel. It was no secret that AndroGel was a blockbuster product. It was bringing in hundreds of millions of dollars annually as of 2011 with a very high profit margin. Sales of AndroGel 1% were \$604 million, \$726 million, and \$874 million in 2009, 2010, and 2011 respectively. The patent attorneys also clearly recognized that the entry of generic versions of AndroGel 1% with their much lower prices would quickly and significantly erode branded AndroGel sales. Their reason and motivation for filing these objectively baseless actions against potential competitors were to staunch, at least for a time, this looming loss of revenue.

253. Since these experienced patent attorneys filed objectively baseless infringement lawsuits, it is reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did. This leads ineluctably to an inference that the subjective intent of the decision-makers was to file sham lawsuits.

254. AbbVie and Besins are not entitled to *Noerr-Pennington* immunity in connection with their filing and maintenance of these sham lawsuits.

S. The Sham Lawsuits Did Not Completely Eliminate the Threat of Teva's and Perrigo's Products To AbbVie's Monopoly

255. Because Teva's and Perrigo's testosterone gel products were filed with the FDA via 505(b)(2) applications rather than ANDAs, the FDA was obligated under the Prescription Drug User Fee Act ("PDUFA") to process the applications within a set period of time. In Teva's case, the original date for completion of FDA review was November 2011.

256. Though the FDA was prevented from issuing final approval to Teva's or Perrigo's products due to the 30-month stays triggered by AbbVie's and Besins's sham patent lawsuits, the

stays would end upon a victory by the generic firm in the district court. In Teva's case, due to the quick trial schedule set by the district court, Teva was likely to receive final FDA approval in 2012.

257. Because of this dynamic, AbbVie recognized the threat from Teva's challenge to its monopoly. On August 8, 2011, AbbVie held a meeting of executives and in-house attorneys to discuss AndroGel. This meeting occurred shortly after Teva filed its motion for summary judgment in AbbVie's patent infringement case against it. During that meeting an executive drew a chart depicting a dramatic erosion of AndroGel sales following entry of an AB-rated generic after a "lost case" eight months hence in April 2012, the month when a hearing on Teva's summary judgment motion was scheduled to occur.

258. Thereafter, AbbVie created "AndroGel Scenarios" with various potential dates for generic entry, including: (1) November 2011, the date by which the FDA had agreed to review Teva's 505(b)(2) application; (2) April 2012, the date on which the summary judgment motion could be decided in the Teva matter; and (3) April 2013, an estimate of the date on which a trial on the merits may have concluded in the Teva matter. In an email on September 30, 2011, an AbbVie executive responsible for the AndroGel franchise characterized the April 2012 entry date as "[t]he most likely scenario."

259. Consistent with AbbVie's expectations, Teva also projected entry in the near-to-medium term. Teva projected that with a November 2011 launch, a non-AB rated generic would be priced significantly below the brand and yield more than \$78 million in sales in 2012, and more than \$116 million in 2013 and in 2014. Teva spent substantial funds preparing to launch, including exploring obtaining a trade name for its product (necessary only if it was not AB-rated). Teva's partner, Cipla, projected "[s]hipment of the finished products" by "May/June 2012." Even after being sued, a Teva executive (Tim Crew) told CEO William Marth in August 2011 that "[w]e

expect to launch the product in 2013” even though “[w]e do not expect a generic AB rating.”

260. Teva also projected, however, that its generic AndroGel 1% would no longer be profitable once 80% of users had switched from AndroGel 1% to AndroGel 1.62%.

261. With AbbVie set to lose the benefit of the 30-month stays their sham lawsuits had triggered, they turned to other ways to preserve their monopoly.

T. AbbVie Paid Teva In The Form Of The TriCor Authorized Generic Deal To Drop Its Patent Challenge And Refrain From Competing Until December 27, 2014

262. In October 2011, the court presiding over AbbVie’s patent litigation against Teva scheduled a bench trial on the dispositive prosecution history estoppel issue for the following May.

263. The early trial date posed a problem for AbbVie. A Teva victory would terminate the 30-month Hatch-Waxman stay, allowing Teva to obtain FDA approval and launch its product. To preserve their monopoly profits and buy more time to shift the market to AndroGel 1.62%, AbbVie needed another way to fend off Teva.

264. After the district court scheduled a May 2012 trial in their patent infringement case against Teva, AbbVie approached Teva to discuss a potential settlement. AbbVie’s goal was to secure a generic entry date that would allow the AbbVie time to shift sales to AndroGel 1.62%.

265. In light of its view that the patent infringement suit was a sham, Teva was not willing to settle for the AbbVie’s preferred entry date absent significant compensation. As asserted by the FTC, Teva asked the AbbVie whether it would be willing to supply Teva with an authorized generic version of TriCor, a cholesterol-reducing drug with annual U.S. sales exceeding \$1 billion in 2011.

266. A generic version of TriCor had been a significant part of Teva’s product pipeline,

but as of late 2011, the project was in trouble. Teva had filed ANDAs with the FDA seeking to market generic versions of 145 mg and 48 mg TriCor tablets. Teva was the first generic challenger on the 145 mg strength and therefore potentially entitled to 180 days of generic marketing exclusivity under the Hatch-Waxman Act. In 2009, Teva had secured a license under an earlier settlement of patent litigation relating to TriCor with AbbVie to launch its 145 mg generic product on July 1, 2012, 180 days before any other generic competitor (including any authorized generic).

267. Because other generics could not launch until January 1, 2013, Teva had expected to enjoy a lucrative “first-mover” advantage, but it was about to lose this opportunity because it had not obtained FDA approval. Over four years after filing its TriCor ANDA, Teva had no viable way of obtaining FDA approval before other competitors were set to launch and had therefore forfeited its 180-day exclusivity rights under applicable Hatch-Waxman provisions. Unless it could secure supply from AbbVie, Teva was poised to lose a valuable first-filer opportunity.

268. The TriCor supply deal would enable Teva to launch in November 2012, seven weeks before other generics, preserving the first-mover advantage. According to the FTC, Teva expected to earn \$175 million in TriCor sales over four years – money that it could not otherwise have earned (and Teva actually sold more than that).

269. Absent eliminating Teva’s threat to its AndroGel franchise, AbbVie had no incentive to increase the likelihood that it would face generic competition from Teva on TriCor, another one of its blockbuster products. If Teva was not able to enter with its own generic TriCor product, then AbbVie would not face generic competition to TriCor until January 1, 2013. AbbVie was willing, however, to supply Teva with authorized generic product before January 1, 2013, but only if Teva would agree to drop its patent challenge and refrain from competing with its generic AndroGel product before December 2014. Teva agreed.

270. According to the FTC, in return for AbbVie's agreement to supply Teva with an authorized generic version of TriCor, a drug with annual U.S. sales exceeding \$1 billion, Teva agreed to settle the AndroGel litigation, dropping its patent challenge and agreeing not to launch generic AndroGel before December 27, 2014.

271. In December 2011, AbbVie and Teva entered into written agreements to settle their AndroGel patent litigation. Under the settlement, Teva agreed to refrain from marketing its 505(b)(2) testosterone gel product until December 27, 2014.

272. AbbVie simultaneously agreed to grant Teva an option to obtain supply of an authorized generic version of TriCor beginning November 10, 2012. The November 10, 2012 launch date was not contingent on the launch of any other generic TriCor product or on Teva's ability to obtain FDA approval for its own generic TriCor ANDA.

273. As asserted by the FTC, when it learned that Teva had agreed to dismiss the "sham infringement lawsuit," Teva's development partner BioSante Pharmaceuticals directly questioned whether Teva received compensation other than a "worthless" patent license in exchange for delaying the launch of its testosterone product:

BioSante finds it incomprehensible that Teva would purport to agree to delay the launch of our FDA-approved 1% testosterone gel product (the "Product") until [December 27, 2014] in exchange for Abbott's dismissal of a sham infringement lawsuit and a license to a worthless patent that does not even read on the Product and likely is invalid. The terms of the Settlement Agreement are so unreasonable for this industry that BioSante questions whether they in fact express the true consideration for Teva's delayed launch.

BioSante did not know that Teva had been separately compensated via the TriCor authorized generic deal. BioSante eventually dropped its complaints after Teva agreed to pay it over \$2 million.

274. AbbVie had no independent, standalone reason to supply Teva with generic TriCor, which would accelerate generic competition on that blockbuster product. But the TriCor deal made perfect sense as a *quid pro quo* for Teva's agreement to foregoing competing with AndroGel. According to the FTC, AbbVie calculated that it would sacrifice about \$100 million in TriCor sales, but that was a small fraction of the billions of dollars in AndroGel revenue AbbVie protected by delaying generic AndroGel competition for three years. And the delay bought AbbVie time to protect the AndroGel franchise by continuing to shift the market to AndroGel 1.62%.

U. The TriCor Authorized Generic Deal Was A Large Payment To Teva

275. The compensation AbbVie agreed to provide Teva via the TriCor authorized generic deal operated as a large payment to Teva. As asserted by the FTC, the payment was designed to, and did, induce Teva to settle the AndroGel patent litigation and agree to refrain from marketing its testosterone gel product until December 2014. Teva's decision to settle was driven not by the strength of AbbVie's patent claims, but by the large payment AbbVie made to Teva via the TriCor authorized generic deal.

276. AbbVie's payment took the form of a TriCor product supply deal that was not otherwise available to Teva. This supply was extremely valuable to Teva. According to the FTC, at the time of its agreement with AbbVie, Teva forecasted that its net sales of authorized generic TriCor under the deal would be nearly \$175 million over a four-year period. Teva's actual generic TriCor sales have exceeded this forecast, making the authorized generic deal worth hundreds of millions of dollars to Teva. These revenues would not have been available to Teva but for its agreement not to launch its 1% testosterone gel product until December 2014.

277. The TriCor authorized generic deal was particularly valuable to Teva because it

allowed Teva to launch generic TriCor before any other generic firm, enabling Teva to secure a valuable first mover advantage, i.e., the lasting advantage in terms of sales of being first to launch. Before its problems with the FDA on its own generic TriCor product, Teva had expected to secure this first mover advantage, and as of the fall of 2011, the investment community continued to view generic TriCor as an important part of Teva's portfolio. Through its deal with AbbVie, Teva was able to secure generic TriCor revenues in 2012 and its first mover advantage.

278. The value of the compensation from AbbVie to Teva in the TriCor authorized generic deal far exceeds either Teva's or AbbVie's actual or saved litigation costs from settlement of the AndroGel patent litigation.

279. The value of the compensation from AbbVie to Teva in the TriCor authorized generic deal exceeds what Teva had projected it was likely to earn had it won the AndroGel patent litigation and marketed its generic testosterone gel product.

280. The TriCor authorized generic deal was something Teva could not have obtained had it won the AndroGel patent infringement litigation. Even if Teva had prevailed in the AndroGel litigation, it would not have secured a right to sell an authorized generic version of TriCor.

V. The TriCor Authorized Generic Deal Is Unjustified.

281. While a sweetheart deal for Teva, the TriCor authorized generic deal cannot be explained as an independent business deal from AbbVie's perspective. Instead, the TriCor authorized generic deal made sense for AbbVie only as a means to induce Teva to drop its patent challenge and refrain from competing with AndroGel until December 2014.

282. Though authorized generic deals are common in the pharmaceutical industry, it is

highly unusual for an authorized generic product to launch significantly before independent generic entry is expected or occurs, other than as consideration in connection with a patent settlement. The reason is a matter of common sense and simple economics: brand-name drug companies who supply the authorized generics have no incentive to compete with themselves and erode their monopoly profits. Authorized generic deals therefore virtually always provide that the product's launch is contingent upon the launch of an independent generic. According to the FTC, there is no such contingency in the TriCor authorized generic deal, nor is Teva's launch contingent on Teva's ability to obtain FDA approval for its TriCor ANDA.

283. Through the TriCor authorized generic deal, AbbVie facilitated generic entry on one of its blockbuster drugs in November 2012, a month and a half earlier than generic entry was otherwise likely to occur. At the time the deal was entered, AbbVie had entered patent settlements with other generic TriCor ANDA filers that prohibited them from marketing generic versions of 145 mg TriCor before January 1, 2013, or from partnering with Teva to do so. Given Teva's failure to secure FDA approval of its own 145 mg generic TriCor ANDA – a fact that was publicly known – generic TriCor 145 mg entry could not have occurred until January 1, 2013, absent the TriCor authorized generic deal.

284. The TriCor authorized generic deal also allowed Teva to launch a 48 mg generic TriCor product on November 10, 2012. Under the terms of AbbVie's prior patent settlement agreements with Teva and other ANDA filers for a 48 mg generic TriCor product, no 48 mg generic TriCor product, including Teva's product, even if approved, could have otherwise entered the market before January 1, 2013.

285. As a result of the TriCor authorized generic deal, Teva launched authorized generic versions of 145 mg and 48 mg TriCor on or about November 16, 2012. Teva's launch triggered

provisions in AbbVie's agreements with other generic TriCor ANDA filers allowing them to launch their own generic TriCor products.

286. According to the FTC, the royalty terms in the TriCor authorized generic deal are significantly worse for AbbVie than the royalty terms in a typical stand-alone authorized generic agreement. In a typical authorized generic deal, the brand-name firm retains a large majority of the profits generated by the product. However, this was not the case for Teva's authorized generic deal for TriCor.

287. The TriCor supply deal lacks any convincing justifications. If AbbVie sought to participate in the market for generic TriCor via an authorized generic product, it could have partnered with a company other than Teva and received a royalty greater than the royalty it received from Teva. With a different arrangement, AbbVie could have profited from generic TriCor sales but also ensured it did not erode more profitable brand-name TriCor sales by accelerating the entry of generic TriCor.

288. According to the FTC, shortly before entering the deal with Teva, AbbVie projected a net loss of roughly \$100 million in TriCor revenues if generic TriCor entered the market in November 2012 (as AbbVie's deal with Teva provided) rather than January 2013. AbbVie's modest income from the TriCor authorized generic deal did not come close to making up this significant loss of revenue.

289. The TriCor agreement and the AndroGel settlement were two sides of a single anticompetitive transaction, as asserted by the FTC. The TriCor authorized generic deal made sense to AbbVie only because it achieved a significant delay in generic AndroGel entry, allowing AbbVie time to shift sales to AndroGel 1.62% and earning AbbVie far more than \$100 million in AndroGel monopoly profits.

290. According to the FTC, AbbVie paid Teva \$175 million to defer launching generic AndroGel until December 2014. During that time, AbbVie was able to shift the vast majority of the market to AndroGel 1.62%. Had there been no sham lawsuit against Teva, there would have been no reverse payment settlement and no agreement not to compete, and thus, Teva would have retained its strong incentive to launch a profitable testosterone gel product as soon as possible, as early as 2012.

W. AbbVie's Agreement With Teva Effectively Blocked Perrigo's Generic AndroGel Entry

291. Soon after the district court scheduled a May 2012 trial in the patent case against Teva, AbbVie approached Teva to discuss a potential settlement. AbbVie's goal was to secure a generic entry date that would allow it time to shift sales to AndroGel 1.62%.

292. On December 20, 2011, AbbVie and Teva entered into written agreements to settle their AndroGel patent litigation. Under the settlement, Teva agreed to refrain from marketing its 505(b)(2) testosterone gel product until December 27, 2014.

293. Almost immediately after filing suit against Perrigo, AbbVie approached Perrigo to discuss a potential settlement.

294. AbbVie could not directly pay Perrigo to delay generic AndroGel entry due to the terms of an FTC consent order Perrigo had entered in 2011. AbbVie could, however, offer Perrigo the right to launch generic AndroGel upon Teva's entry. This term was valuable to Perrigo because Teva appeared more likely than Perrigo to achieve a quick victory in the patent litigation and end the 30-month stay triggered by AbbVie's sham lawsuit. Teva had obtained a quick May 2012 trial date and, as reflected in Teva's antitrust counterclaims, seemed likely to press its position and win.

295. AbbVie's lawsuit against Perrigo, in contrast, had been filed in a different judicial

district and Perrigo believed that its case was unlikely to end before the suit against Teva. A settlement, therefore, provided Perrigo with an opportunity to achieve parity with Teva (that is, the same entry date) without expending any litigation costs. Without a settlement, Perrigo would have been unable to achieve parity with Teva because the 30-month stay blocking FDA approval of Perrigo's product would remain in effect.

296. On December 8, 2011, AbbVie and Perrigo agreed to settle their patent litigation. The settlement provided that Perrigo could launch generic AndroGel 1% upon the launch of another generic AndroGel product (including Teva's testosterone gel product) or no later than January 1, 2015. Perrigo had been monitoring the Teva litigation and thought Teva would prevail at the trial scheduled for May 2012 and thereafter launch its product, so "that would provide a much earlier Perrigo license date." As a result of the Teva settlement, Perrigo's licensed entry date was moved to December 27, 2014 – the same date as Teva's – under the acceleration clause in the AbbVie-Perrigo settlement.

297. Perrigo's decision to settle was driven not by the strength of the patent claims against it (which were baseless) but by the competitive position Perrigo found itself in as a result of the 30-month stay triggered by AbbVie's and Besins's sham suit, and the opportunity to improve that position by achieving parity with Teva. But as AbbVie knew – and Perrigo did not – AbbVie was in the process of negotiating a deal with Teva that would delay Teva's entry well beyond what Perrigo expected.

298. By securing Teva's agreement to forgo entry until December 2014, AbbVie blocked competition from Perrigo as well. Because of the terms of Perrigo's settlement, the Teva agreement effectively protected AbbVie against Perrigo's generic AndroGel 1% entry until December 27, 2014.

V. MARKET POWER AND RELEVANT MARKET

299. At all relevant times, AbbVie had market power with respect to AndroGel because it had the power to maintain the price of AndroGel at supracompetitive levels without losing substantial sales to other testosterone replacement therapies. This market power may be shown directly, and therefore no relevant market needs to be defined. As the Supreme Court stated in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), the fact that AbbVie made large reverse payments to their generic competitors is itself evidence of market power.

300. To the extent a relevant product market must be defined, the relevant product market at issue in this case is AndroGel 1%, and AB-rated bioequivalent generic versions of AndroGel 1% and BX-rated generic versions of AndroGel 1%. Even if, *arguendo*, AndroGel 1.62% were considered part of the relevant antitrust market, AbbVie still had 100% of that market until Perrigo began to sell generic AndroGel 1% in December 2014.

301. A small but significant, non-transitory price increase for branded AndroGel 1% did not cause a significant loss of sales to other medications sufficient to make such a price increase unprofitable.

302. AndroGel 1% does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of AndroGel 1% (no BX-rated version was launched).

303. The FDA does not consider AndroGel 1% and other medications to be interchangeable.

304. Price does not drive prescriptions for AndroGel 1% or other TRTs. The pharmaceutical marketplace is characterized by a “disconnect” between the payment obligation

and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including AndroGel, to patients without a prescription written by a doctor. This prohibition introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

305. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

306. AbbVie needed to control only AndroGel 1% and its AB-rated and BX-rated generic equivalents, and no other products, in order to maintain the price of AndroGel 1% profitably at supra-competitive prices. Only the market entry of a competing, AB-rated or BX-rated generic version of AndroGel 1% would have rendered AbbVie unable to profitably maintain its prices of AndroGel 1% without losing substantial sales.

307. The entry of other brands of TRT medications (or generic versions of those other brands) other than the AndroGel franchise line extension of AndroGel 1.62% did not cause AbbVie to lower its price. The entry of other brands of TRT (other than AndroGel 1.62%) did not take substantial sales from AndroGel 1%. By contrast, the competitive impact of an AB-rated or BX-rated generic version of AndroGel 1% on brand AndroGel 1% was expected to be and was substantial. Among other things, the actual entry of an AB-rated generic AndroGel 1% in 2014 delivered substantial savings to purchasers.

308. At all relevant times, AbbVie sold AndroGel 1% at prices well in excess of the competitive price and enjoyed high profit margins.

309. At all relevant times, AbbVie had, and exercised, the power to exclude and restrict competition to AndroGel 1% and its AB-rated bioequivalents and BX-rated versions.

310. At all relevant times, AbbVie enjoyed high barriers to entry with respect to competition in the relevant product market due to regulatory protections and high costs of entry and expansion.

311. The relevant geographic market is the United States and its territories, possessions and commonwealth of Puerto Rico.

312. If required, AbbVie's market and monopoly power over AndroGel 1% can be shown through circumstantial evidence, including a high share of a relevant market of AndroGel 1% and its AB-rated and BX-rated generics (or alternatively, a relevant market that includes AndroGel 1.62%), and with evidence of substantial barriers to entry.

VI. MARKET EFFECTS AND DAMAGES

313. Typically, generic drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated and rapidly replace the brand drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers. As discussed above, Teva projected that a BX-rated generic version of AndroGel 1% would also achieve significant sales at a lower price than the brand.

314. This price competition enables all purchasers of the drug to, *inter alia*: (a) purchase generic versions of a drug at substantially lower prices than the brand; and (b) purchase generic equivalents of the drug at a lower price, sooner. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers suffer substantial

cost inflation from that delay and impairment.

315. But for the anticompetitive conduct alleged above, Watson and/or Par/Paddock would have entered the market with a generic version of AndroGel 1% in 2007, or at some later time but earlier than they actually did, whether by launching before the patent infringement litigation was over, or after they prevailed, or pursuant to an alternative settlement that did not contain large reverse payments but provided for an earlier generic entry date.¹⁴ At least one additional generic (likely an authorized generic) would have launched on or about the same time, or earlier. Additionally, as Judge Bartle found, Perrigo would have entered the market with its generic version of AndroGel 1% no later than June 2013 but for the sham lawsuit filed by AbbVie. And but for the sham lawsuit and reverse payment in the form of the TriCor authorized generic deal, Teva would have entered in June 2012 or thereafter with (at least) a BX-rated version of AndroGel 1%. An authorized generic likely would have launched whenever (at least) AB-rated generic competition began.

316. A significant portion of AndroGel 1% sales has shifted to AndroGel 1.62% since 2012, a shift made possible by Defendants' anticompetitive conduct. Because generic AndroGel 1% products are not automatically substitutable for brand-name AndroGel 1.62%, purchasers realized fewer benefits from generic AndroGel 1% competition than they would have had generic AndroGel 1% entered earlier. Plaintiffs purchased more branded AndroGel 1% and 1.62% than they would have had generic AndroGel 1% entered earlier, and paid more for the brand than they would have for the generic.

¹⁴ See *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013) (brand and generic companies can still “settle in other ways, for example, by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”).

317. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting AndroGel from generic competition.

318. Watson (and its successors) and Par/Paddock, as well as Teva and Perrigo, have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand.

319. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of AndroGel 1%, has caused Plaintiffs to pay more than they would have paid for AndroGel 1% and 1.62% and/or generic AndroGel 1% than they would have paid absent Defendants' illegal conduct.

320. But for Defendants' anticompetitive conduct, Plaintiffs would have paid less for AndroGel 1% and 1.62% and/or generic AndroGel 1% by, *inter alia*: (a) substituting purchases of less-expensive generic AndroGel 1% for their purchases of more-expensive branded AndroGel 1% and/or branded AndroGel 1.62%; and/or (b) purchasing generic AndroGel 1% at lower prices sooner. As a consequence of the unlawful conduct alleged herein, Plaintiffs have sustained substantial losses to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

321. Thus, Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

VII. ANTITRUST IMPACT

322. During the relevant period, Plaintiffs purchased substantial amounts of AndroGel

1% and 1.62% directly from AbbVie and purchased generic AndroGel 1% directly from generic manufacturers. As a result of Defendants' illegal conduct, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their AndroGel 1% and 1.62% requirements, and for generic AndroGel 1%. Those prices were substantially higher than the prices that Plaintiffs would have paid absent the illegal conduct alleged herein.

323. But for the unlawful conduct alleged herein, Plaintiffs would have paid less for AndroGel 1% and 1.62% and/or generic AndroGel 1% by, *inter alia*: (a) substituting purchases of less-expensive generic AndroGel 1% for their purchases of more-expensive branded AndroGel 1% and/or branded AndroGel 1.62%; and/or (b) purchasing generic AndroGel 1% at lower prices sooner. As a consequence of the unlawful conduct alleged herein, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

VIII. EFFECT ON INTERSTATE COMMERCE

324. At all material times, AndroGel, manufactured by Besins and sold by AbbVie, was shipped across state lines and sold to customers located outside its state of manufacture.

325. During the relevant time period, in connection with the purchase and sale of AndroGel, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

326. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. Defendants' activities were within the flow of, and have substantially affected, interstate commerce.

IX. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 2 (UNLAWFUL MAINTENANCE AND EXTENSION OF MONOPOLY THROUGH OVERARCHING CONSPIRACY) AGAINST ABBVIE

327. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

328. At all relevant times, AbbVie and their predecessors possessed substantial market power (i.e. monopoly power) in the relevant market, including the power to raise and maintain supra-competitive prices and exclude competitors from the relevant market.

329. AbbVie was engaged in an overarching multi-part, exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the AndroGel market. AbbVie's scheme included:

- a. improperly listing the '894 patent in the Orange Book while knowing that as issued it did not claim AndroGel or its approved use, was invalid and/or was unenforceable;
- b. agreeing to make a series of large and unjustified payments beginning in 2006 to Watson and Par/Paddock to delay generic entry of AndroGel from 2007 to 2015;
- c. entering into reverse payment agreements with Watson and Par/Paddock to delay generic entry in order to develop and switch prescriptions to an AndroGel line extension (1.62%) to thwart generic competition after the reverse payment agreements expired in 2015;
- d. entering into market allocation agreements with would-be competitors Watson and Par/Paddock under which Watson and Par/Paddock would share in the profits from branded AndroGel sales in exchange for delaying their competitive market entry until August 31, 2015;
- e. filing sham lawsuits against generic manufacturers Teva and Perrigo without regard for the merits and with the intent to delay generic entry and with the effect of delaying generic entry;
- f. agreeing to make a large and unjustified payment beginning in 2011 to Teva to delay generic entry of AndroGel from 2012 to 2014; and
- g. filing sham lawsuits against Perrigo and Teva and entering into a reverse payment

agreement with Teva to delay generic entry in order to develop and switch prescriptions to an AndroGel line extension (1.62%) to further thwart and impair generic competition after generics belatedly entered.

330. The overarching multi-part conspiracy alleged herein was undertaken with the specific intent to monopolize the market for AndroGel 1% in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

331. As a result of this unlawful maintenance and extension of monopoly power, Plaintiffs paid artificially-inflated prices for their AndroGel 1% and AndroGel 1.62% purchases, and/or for generic AndroGel 1%. But for AbbVie's illegal conduct, competitors would have begun marketing generic versions of AndroGel 1% sooner, and/or would have marketed such versions more successfully and sold their generic versions at lower prices than they actually did.

332. The goal, purpose, and/or effect of AbbVie's misconduct was to maintain and extend their monopoly power with respect to AndroGel. AbbVie's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of competition from any generic version of AndroGel 1%, enabled them to continue charging supra-competitive prices for AndroGel 1% and AndroGel 1.62% without a substantial loss of sales.

333. If manufacturers of generic AndroGel 1% had been able to enter the market and fairly compete with AbbVie in a full and timely fashion, Plaintiffs would have substituted lower-priced generic AndroGel 1% for some or all of their AndroGel 1% and/or AndroGel 1.62% requirements, and/or would have been able to purchase generic AndroGel 1% at lower prices than they actually did.

334. During the relevant period, Plaintiffs purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie, and purchased generic AndroGel 1% directly from generic

manufacturers. As a result of AbbVie's illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, prices for AndroGel 1% and 1.62% and/or generic AndroGel 1% that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because *inter alia*: (a) Plaintiffs were deprived of the opportunity to purchase lower-priced generic AndroGel 1% instead of expensive brand-name AndroGel 1% and AndroGel 1.62%; and/or (b) the price of generic AndroGel 1% was higher than it would have been but for AbbVie's illegal conduct.

335. But for the unlawful conduct alleged herein, Plaintiffs would have paid less for AndroGel 1% and 1.62% and/or generic AndroGel 1% by, *inter alia*: (a) substituting purchases of less-expensive generic AndroGel 1% for their purchases of more-expensive branded AndroGel 1% and/or branded AndroGel 1.62%; and/or (b) purchasing generic AndroGel 1% at lower prices sooner. As a consequence of the unlawful conduct alleged herein, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

**CLAIM II: VIOLATION OF 15 U.S.C. § 1
(ANTI-COMPETITIVE REVERSE PAYMENT AGREEMENT) AGAINST
ABBVIE AND WATSON AND ITS SUCCESSORS**

336. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

337. In or about September 2006, AbbVie agreed to pay Watson hundreds of millions of dollars to induce Watson to give up its challenge to the '894 patent and delay its generic entry for nine years until at the earliest August 31, 2015. AbbVie agreed to pay Watson through a

pretextual co-promotion agreement, entered on the same day as the settlement of the patent litigation. The reverse payment agreement with Watson constituted a continuing illegal contract, combination and conspiracy in restraint of trade under which AbbVie paid Watson and its successors large and unjustified reverse payments in exchange for Watson's (and its successors') agreement to delay bringing their generic versions of AndroGel 1% to the market.

338. The purpose and effect of the reverse payment agreement was to prevent the sale of generic versions of AndroGel 1% in the United States, thereby protecting AndroGel from any generic competition until 2015 and fix the price at which direct purchasers would pay for AndroGel at supracompetitive levels.

339. The agreement harmed Plaintiffs by causing them to be overcharged.

340. The reverse payment agreement covered the entirety of the relevant market so that it harmed competition.

341. AbbVie and Watson are liable for the reverse payment agreements under a rule of reason standard (if not a *per se* standard).

342. There is no legitimate, non-pretextual, procompetitive business justification for the reverse payments that outweighs their harmful effect.

343. During the relevant period, Plaintiffs purchased AndroGel 1% and 1.62% directly from AbbVie and purchased generic AndroGel 1% directly from generic manufacturers. But for the unlawful reverse payment agreement between AbbVie and Watson and its successors, Watson or its successors would have launched generic AndroGel 1% sooner than they actually did, and at least one other generic (including an authorized generic) would have launched at about the same time. As a direct and proximate result of Defendants' anticompetitive conduct, Plaintiffs were

harmful by being overcharged on their purchases of branded AndroGel 1% and 1.62% and on their purchases of generic AndroGel 1%. As a result of the illegal conduct alleged herein, Plaintiffs were compelled to pay, and did pay, prices for AndroGel 1% and AndroGel 1.62% and/or for generic AndroGel 1% that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because *inter alia*: (a) Plaintiffs were deprived of the opportunity to purchase lower-priced generic AndroGel 1% instead of expensive brand-name AndroGel 1% and AndroGel 1.62%; and/or (b) the price of generic AndroGel 1% was higher than it would have been but for Defendants' illegal conduct.

344. But for the unlawful conduct alleged herein, Plaintiffs would have paid less for AndroGel 1% and 1.62% and/or generic AndroGel 1% by, *inter alia*: (a) substituting purchases of less-expensive generic AndroGel 1% for their purchases of more-expensive branded AndroGel 1% and/or branded AndroGel 1.62%; and/or (b) purchasing generic AndroGel 1% at lower prices sooner. As a consequence of the unlawful conduct alleged herein, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

**CLAIM III: VIOLATION OF 15 U.S.C. § 1
(ANTI-COMPETITIVE REVERSE PAYMENT AGREEMENT) AGAINST
ABBVIE AND PAR/PADDOCK**

345. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

346. In or about September 2006, AbbVie agreed to pay Par/Paddock tens of millions of dollars to induce Par/Paddock to give up its challenge to the '894 patent and delay its generic entry

for nine years until at the earliest August 31, 2015. AbbVie agreed to pay Par/Paddock through pretextual co-promotion and back-up manufacturing agreements, entered on the same day as the settlement of the patent litigation. The reverse payment agreements with Par/Paddock constituted continuing illegal contracts, combinations and conspiracies in restraint of trade under which AbbVie paid Par/Paddock and their successors large and unjustified reverse payments in exchange for Par/Paddock's (and their successors') agreement to delay bringing their generic versions of AndroGel 1% to the market.

347. The purpose and effect of the reverse payment agreements were to prevent the sale of generic versions of AndroGel 1% in the United States, thereby protecting AndroGel from any generic competition until 2015 and fix the price at which direct purchasers would pay for AndroGel at supracompetitive levels.

348. The agreements harmed Plaintiffs by causing them to be overcharged.

349. The reverse payment agreements covered the entirety of the relevant market so that they harmed competition.

350. AbbVie and Par/Paddock are liable for the reverse payment agreements under a rule of reason standard (if not a *per se* standard).

351. There is no legitimate, non-pretextual, procompetitive business justification for the reverse payments that outweighs their harmful effect.

352. During the relevant period, Plaintiffs purchased AndroGel 1% and 1.62% directly from AbbVie and purchased generic AndroGel 1% directly from generic manufacturers. But for the unlawful reverse payment agreement between AbbVie and Par/Paddock, Par/Paddock would have launched generic AndroGel 1% sooner than they actually did, and at least one other generic

(including an authorized generic) would have launched at about the same time. As a direct and proximate result of Defendants' anticompetitive conduct, Plaintiffs were harmed by being overcharged on their purchases of branded AndroGel 1% and 1.62% and/or on their purchases of generic AndroGel 1%. Plaintiffs were compelled to pay, and did pay, prices for AndroGel 1% and AndroGel 1.62% and/or for generic AndroGel 1% that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because *inter alia*: (a) Plaintiffs were deprived of the opportunity to purchase lower-priced generic AndroGel 1% instead of expensive brand-name AndroGel 1% and AndroGel 1.62%; and/or (b) the price of generic AndroGel 1% was higher than it would have been but for Defendants' illegal conduct.

353. But for the unlawful conduct alleged herein, Plaintiffs would have paid less for AndroGel 1% and 1.62% and/or generic AndroGel 1% by, *inter alia*: (a) substituting purchases of less-expensive generic AndroGel 1% for their purchases of more-expensive branded AndroGel 1% and/or branded AndroGel 1.62%; and/or (b) purchasing generic AndroGel 1% at lower prices sooner. As a consequence of the unlawful conduct alleged herein, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

**CLAIM IV: VIOLATION OF 15 U.S.C. § 2
(UNLAWFUL MAINTENANCE AND EXTENSION OF MONOPOLY
THROUGH SHAM LITIGATION) AGAINST ABBVIE AND BESINS**

354. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

355. At all relevant times, AbbVie and Besins possessed substantial market power (*i.e.* monopoly power) in the relevant market, including the power to raise and maintain supra-

competitive prices and exclude competitors from the relevant market.

356. AbbVie and Besins filed sham litigation against generic manufacturers Teva and Perrigo in 2011 to maintain and extend their monopoly in the AndroGel market. The sham lawsuits were filed without regard for the merits and with the intent to delay generic entry.

357. The sham litigation alleged herein was undertaken with the specific intent to monopolize the market for AndroGel 1% in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

358. As a result of this unlawful maintenance and extension of monopoly power, Plaintiffs paid artificially-inflated prices for their AndroGel 1% and AndroGel 1.62% requirements, and/or for generic AndroGel 1%. But for AbbVie's and Besins's illegal conduct, Perrigo and/or Teva would have begun marketing generic versions of AndroGel 1% earlier than December 2014, when Perrigo actually launched its generic; at least one other generic including an authorized generic would have launched at about the same time (assuming such additional generic competition had not already begun previously); and/or Perrigo would have marketed its generic version more successfully and sold it at lower prices than it actually did or that Plaintiffs were otherwise paying.

359. The goal, purpose, and/or effect of AbbVie's and Besins's misconduct was to maintain and extend their monopoly power with respect to AndroGel. AbbVie's and Besins's illegal conduct, which was calculated and designed to prevent, delay, and/or minimize the success of competition from any generic version of AndroGel 1%, enabled them to continue charging supra-competitive prices for AndroGel 1% and AndroGel 1.62% without a substantial loss of sales.

360. If manufacturers of generic AndroGel 1% had been able to enter the market and

fairly compete with AbbVie in a full and timely fashion, Plaintiffs would have substituted lower-lower priced generic AndroGel 1% for some or all of their AndroGel 1% and/or AndroGel 1.62% purchases, and/or would have been able to purchase generic AndroGel 1% at lower prices than they actually did.

361. During the relevant period, Plaintiffs purchased AndroGel 1% and AndroGel 1.62% directly from AbbVie and purchased generic AndroGel 1% directly from generic manufacturers. As a result of AbbVie's and Besins's illegal conduct, alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their AndroGel 1% and AndroGel 1.62% and/or generic AndroGel 1% requirements. Plaintiffs paid prices for AndroGel 1% and AndroGel 1.62% and/or generic AndroGel 1% that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because *inter alia*: (a) Plaintiffs were deprived of the opportunity to purchase lower-priced generic AndroGel 1% instead of expensive brand-name AndroGel 1% and AndroGel 1.62%; and/or (b) the price of generic AndroGel 1% was higher than it would have been but for AbbVie's and Besins's illegal conduct.

362. But for the unlawful conduct alleged herein, Plaintiffs would have paid less for AndroGel 1% and 1.62% and/or generic AndroGel 1% by, *inter alia*: (a) substituting purchases of less-expensive generic AndroGel 1% for their purchases of more-expensive branded AndroGel 1% and/or branded AndroGel 1.62%; and/or (b) purchasing generic AndroGel 1% at lower prices sooner. As a consequence of the unlawful conduct alleged herein, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

**CLAIM V: VIOLATION OF 15 U.S.C. § 1
(ANTI-COMPETITIVE REVERSE PAYMENT AGREEMENT) AGAINST
ABBVIE AND TEVA**

363. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

364. In or about December 2011, AbbVie and Teva entered into a reverse payment agreement, which constituted a continuing illegal contract, combination and conspiracy in restraint of trade under which AbbVie paid Teva a large and unjustified reverse payment in exchange for Teva's agreement to refrain from marketing its 505(b)(2) testosterone gel product until December 27, 2014. AbbVie's payment to Teva was in the form of an agreement to supply Teva with an authorized generic version of TriCor, a drug with annual U.S. sales exceeding \$1 billion.

365. The purpose and effect of the reverse payment agreement was to prevent the sale of generic versions of AndroGel 1% in the United States, thereby protecting AndroGel from any generic competition until December 2014 and fix the price at which direct purchasers would pay for AndroGel at supracompetitive levels.

366. The agreement harmed Plaintiffs by causing them to be overcharged.

367. The reverse payment agreements covered the entirety of the relevant market so that they harmed competition.

368. Defendants AbbVie and Teva are liable for the reverse payment agreement under a rule of reason standard. Alternatively, they are liable under a *per se* standard because AbbVie's patent infringement lawsuit against Teva was a sham.

369. There is no legitimate, non-pretextual, procompetitive business justification for the reverse payments that outweighs their harmful effect.

370. During the relevant period, Plaintiffs purchased AndroGel 1% and 1.62% directly from AbbVie and purchased generic AndroGel 1% directly from generic manufacturers. But for the unlawful reverse payment agreement between AbbVie and Teva, Teva would have launched generic AndroGel 1% sooner than it agreed to in its unlawful agreement. As a direct and proximate result of Defendants' anticompetitive conduct, Plaintiffs were harmed by being overcharged on their purchases of branded AndroGel 1% and 1.62% and on their purchases of generic AndroGel 1%. Plaintiffs were compelled to pay, and did pay, prices for AndroGel 1% and AndroGel 1.62% and/or generic AndroGel 1% that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because *inter alia*: (a) Plaintiffs were deprived of the opportunity to purchase lower-priced generic AndroGel 1% instead of expensive brand-name AndroGel 1% and AndroGel 1.62%; and/or (b) the price of generic AndroGel 1% was higher than it would have been but for Defendants' illegal conduct.

371. But for the unlawful conduct alleged herein, Plaintiffs would have paid less for AndroGel 1% and 1.62% and/or generic AndroGel 1% by, *inter alia*: (a) substituting purchases of less-expensive generic AndroGel 1% for their purchases of more-expensive branded AndroGel 1% and/or branded AndroGel 1.62%; and/or (b) purchasing generic AndroGel 1% at lower prices sooner. As a consequence of the unlawful conduct alleged herein, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs respectfully requests that the Court:

A. Enter joint and several judgments against Defendants and in favor of Plaintiffs;

B. Adjudge the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), to be an unlawful restraint of trade and unlawful maintenance of monopoly in violation of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

C. Award Plaintiffs damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

D. Award Plaintiffs their costs of suit, including reasonable attorneys' fees as provided by law.

XI. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs demand a trial by jury on all issues so triable.

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Respectfully submitted,

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